

**Report on Review and Assessment of Purdue University's Actions in
Connection with the Camp DASH Research Study**



**Submitted to President Mitchell E. Daniels, Jr.
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**by
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Introduction

On July 27, 2017,¹ Purdue University President Mitchell E. Daniels, Jr. requested that I lead an institutional review and assessment of the University's actions in connection with Camp Dash 2017, and to prepare this report for public release of my conclusions and recommendations.

In conducting the review and assessment, I was guided by two principles:

1. Purdue University is committed to the safety and security of all individuals who participate in University programs and activities.
2. All research conducted under the auspices of Purdue University that involves human subjects should be conducted ethically and in a manner that promotes the protection of the rights and welfare of human subjects.

Purdue seeks to fulfill its commitment to safety and security through the employment of personnel specifically tasked with carrying out duties in these areas and through the adoption of policies and procedures designed to mitigate the risks and impacts of certain behaviors and activities (e.g., Operating Procedures for Programs Involving Minors, Violent Behavior and Use of University Vehicles for University Business).

The Participants were recruited and paid by Purdue to participate in the Study. Because the Participants were children, their parents/guardians were requested to and granted permission to Purdue to have 24/7 custody of the Participants during their enrollment in the Study. Because of their ages and participation in a research study, the University had heightened responsibilities to ensure the safety and welfare of the Participants.

Individuals, departments and programs with responsibility for the safety and welfare of the Participants included:

- Study PI, Research Team, Counselors and Staff;
- Human Research Protection Program, Institutional Review Board ["IRB"];
- Purdue University Police Department ["PUPD"];
- Purdue University Fire Department ["PUFD"]; and
- University Residences

Methodology

I was assisted in the review and assessment by legal counsel who interviewed the following: Dr. Connie Weaver, Distinguished Professor of Nutrition Science and Principal Investigator ["PI"]; Dr. Berdine Martin, Research Scientist, Department of Nutrition Science, and Project Manager; DeWayne Moffitt, Camp Manager; Robin Rhine, Human Clinical Services Coordinator, Department of Nutrition Science; a graduate student researcher on the Study; the Study's seven Head Counselors and several Counselors with knowledge of specific incidents; Dr. Michele Forman, Head of the Department of Nutrition Science, Dr. Christine Ladisch, Dean of the

¹ See Appendix, Exhibit 1, memo dated July 27, 2017, from Mitchell E. Daniels, Jr. to Alysa Christmas Rollock.

College of Health and Human Services, Dr. Jay Akridge, Interim Executive Vice President for Academic Affairs, Provost and Chief Diversity Officer; Drs. Howard Zelaznik, Stephen Elliott and Jeannie DiClementi who acted on behalf of Purdue's Human Subjects Protection Program; Barbara Frazee, Kyla Houston and Lee Morrison from University Residences; John Cox and Keene Red Elk from the PUPD, Trenten Klingerman, Assistant Legal Counsel; Jamie Goodfellow, Assistant Director of Administration and Conferences; Carol Shelby, Senior Director of Environmental Health and Public Safety; and parents of a number of Participants.

We reviewed survey responses from the parents/guardians of Participants and relevant documents, including but not limited to, emails, text messages, social media items, incident reports, the Study protocol, amendments and budget materials, training materials and records, and correspondence and materials furnished to Conferences, Risk Management, University Residences, the IRB, NIH and collaborating institutions.

We also inspected the facilities used by the Participants and considered information furnished to us by University employees with knowledge of incidents involving the Participants.

Executive Summary

Background

Camp DASH is part of a five-year federally funded research study: Trial of Dietary Patterns and Sodium Reduction on Blood Pressure in Adolescents ["the Study"]. It is a dietary intervention for 11-to-15 year old boys and girls whose blood pressure is in the upper third of systolic blood pressure distribution for gender, age, and height. Participants in the Study were to be given two of four diets with one diet in the first 25 day session and a different diet in the second 25 day session. In addition to a controlled diet, the Study included a number of physiological tests.

Researchers selected and paid the Participants to live on campus during the sessions. The camp portion of the Study was designed to provide the Participants with recreation and enriching activities when not occupied with the feeding, testing or measurements required by the Study.

Difficulties with the operations of Camp DASH began shortly after the arrival of the Participants. During the first week, two Participants were arrested and dismissed from the Study for committing acts of violence against fellow Participants, and one Participant required transport to a hospital for medical treatment as a result of the violence. PUPD officers also responded to altercations among the Participants on two additional occasions. In response, a meeting was held among University stakeholders, including representatives from the Study, PUPD and University Residences. As a result, action items to improve safety and reporting were developed and disseminated to Counselors and Study staff. In addition, the IRB notified the PI that the Study would be suspended if "another event occurs prior to July 5, 2017."

Notwithstanding these interventions, behavioral issues among a number of the Participants (including, violent assaults, sexual harassment, inappropriate touching, bullying, fighting and intimidation) and other problems (most notably, the failure to report incidents in a timely

fashion) continued during Session 1. In response to these continued problems, on June 30, 2017 PUPD Chief Cox informed Dr. Zelaznik, then Associate Vice President for Research (with copies to representatives of University Residences, the Co-Rec and the Office of Legal Counsel) that, "[i]t is now my position there is an imminent threat to the health and safety of the children attending camp DASH.... Based on the information documented in past incident, information that children are still being harmed or committing crimes ... and incidents are not being report [sic] to police and/or University Residences as mandated and this latest act of violence towards a camp counselor, I recommend camp DASH be cancelled and the campers sent home."

During the period June 30-July 4, 2017, University administrators considered whether the camp portion of the Study ought to be suspended or terminated. In response to interventions and enhancements outlined by the PI, Chief Cox indicated that he could support continuing the camp if "[p]rogram management actually follows through on what they say they are going to do" and "[t]here is immediate reporting of behaviors that are illegal or violate university policy as they have been instructed in the past." Chief Cox also stated that if "a camper commits another violent act against another camper, the program should be shut down immediately."

Unknown to Dr. Akridge and those involved in the decision to continue the camp portion of the Study, serious incidents involving sexual harassment and misconduct by a male Participant against several female Participants and violent actions of a male Participant against other Participants, had not been reported to anyone outside of the Study. Each of these events was known to Dr. Weaver, but not reported to the IRB until July 5, 2017.

During the period July 5-10, 2017, the Participants went home for the scheduled break between Session 1 and Session 2.

In preparation for Session 2, and in accordance with the agreed upon enhancements and interventions, a Camp Manager was hired and began his employment on July 10, 2017. The Camp Manager was tasked with direct supervision of Head Counselors and Counselors, and was authorized to dismiss Participants independently of the PI. Additional training was held for Counselors and Study Staff that included safety and reporting requirements and guidelines and topics addressed to Participant issues, including bullying, self-harm and appropriate conduct. In addition, regular stakeholder meetings were instituted. Notwithstanding the implementation of these measures, additional incidents of misconduct and disruptive behavior continued during Session 2.

On July 19, PUPD received reports regarding the posting on social media of a nude video of one of the female Participants by another female Participant. Later that day, details regarding the incident and his recommendation that the camp portion of the Study be shut down was conveyed by Chief Cox to Dr. Akridge, who agreed that the shutdown was necessary to protect the safety and welfare of the Participants. On July 20, 2017, Dr. Weaver was informed that the University was closing the camp portion of the Study because the Participants were not adequately supervised and protected. Following notification of parents/guardians, the remaining 46 Participants were sent home on July 21, 2017.

Key Findings

The design of Camp DASH was inadequate.

The design of Camp DASH was inadequate to provide a safe environment for all of the Participants. Areas of inadequacy included:

- Supervision of Participants
- Supervision of camp staff (Head Counselors and Counselors)
- Staffing (number, qualifications, certifications/licenses, and training)
- Screening of Participants
- Programming for Participants
- Budget
- Living accommodations

Camp DASH suffered from a culture of non-compliance.

Although there were policies, procedures, rules and protocols in place that might have prevented or addressed many of the problems that arose in connection with Camp DASH, there was a culture of non-compliance that exacerbated or contributed directly to the problems in the operation and management of Camp DASH and to harm suffered by Participants, Counselors and Study staff. Examples of non-compliance included:

- Multiple failures to comply with University policies and procedures
- Failure to complete required background checks
- Failure to complete CITI training
- Failure to comply with University Residences rules
- Failure to report suspected child abuse, including sexual exploitation of a minor, and sexual harassment in a timely manner
- Multiple deviations from the Study protocol
 - No registered nurse on staff
 - Blood pressure measurement training not conducted as stated in protocol
 - Collection of data after the IRB changed status to Data Analysis Only (and after the University closed Camp DASH)
- Multiple failures to implement additional controls and enhancements
 - Lack of candor to University administrators
 - Failure to implement items promised on June 15, 2017
 - Failure to implement processes and procedures promised on July 2, 2017
 - Failure to comply with the conditions for the continuation of the Study imposed by the Provost on July 4, 2017

Key Recommendations regarding the Study

Given the findings outlined above, the University should consider the following:

- whether any or all of the data collected in the Study may be used by the PI and Researchers;
- whether the University ought to permit the camp portion of the Study to resume, and if so, under what conditions; and
- imposing appropriate remediation and/or sanctions for individuals whose action or inaction contributed to the harm suffered by Participants, Counselors and Study staff.

Key Recommendations regarding Youth Programming

The University should

- review and consider adoption of standards established by the American Camp Association, the Camp Nursing Association and the Higher Education Protection Network;
- establish a standing committee to undertake an annual review of risks associated with youth camps and programs hosted by or at the University, and to make recommendations for necessary revisions to policies and practices; and
- consider the creation of a position whose responsibility will be to oversee compliance by youth programs and camps with University policies and practices relating to youth safety and reporting.

Overview of the Study

Dr. Connie Weaver, Distinguished Professor of Nutrition Science, is the PI of the Study. The Study is funded by a five year grant totaling \$8.8 million from the National Institutes of Health ["NIH"]. The concept for the study that was named "Camp DASII"² was based on a series of eleven earlier studies conducted by the PI and her research team that are collectively called "Camp Calcium." These feeding studies were also NIH-funded and conducted during the period from 1990 to 2014. According to the PI's website, those controlled feeding studies "were run as summer research camps (i.e. "camp calcium") to determine diet, sex, and racial influences on metabolism of calcium and other bone minerals.³ The research results from Camp Calcium led to the establishment of bone mineral requirements for adolescents.

According to the Proposed Research Rationale for the Study, in adults, the DASH diet has been shown to be effective at reducing blood pressure and lowering LDL cholesterol. The purpose of the Study is to determine the effect of the DASH diet and sodium intake in children and adolescents.

² DASH is an acronym for Dietary Approaches to Stop Hypertension diet.

³ https://www.purdue.edu/hhs/nutr/directory/faculty/weaver_connie.html

[REDACTED]

The design of the Study is a controlled feeding program to be conducted over the course of four summers. [REDACTED]

[REDACTED]

[REDACTED] The Study design called for Participants to live in a residence hall on the West Lafayette campus of Purdue.

[REDACTED]

In time not devoted to collecting measurements, Participants will engage in activities such as sports, science and nutrition classes, arts and crafts, and field trips. Participants will be paid \$15 per day of attendance (a total of \$750 for the entire camp). There is an activity fee of \$100 per session which could be deducted from the payment to the Participant. Room and board are free for the Participants.

[REDACTED]

[REDACTED] The PI and her research team ["the Researchers"] had planned to have 150 Participants during the summer of 2017. However, on the first day of Session 1 of the first year of the Study, June 10, 2017, seventy-eight Participants arrived.

[REDACTED]

⁵ The largest participant population of Camp Calcium was 85. The participant goal for 3 summers of the Study was 150 for three of the four years and 72 participants during year 3. There were 78 participants at the beginning of Session 1 of Camp Dash. An additional Participant arrived one week after the start of Session 1.

Researchers started recruiting Participants in February 2017 which was later than planned due to an issue with sending post cards to families with children who would likely meet the blood pressure requirement by the Indiana Clinical and Translational Sciences Institute. Recruiting of Participants was conducted by the Researchers in Lafayette and Indianapolis, Indiana. In Chicago, Illinois, a clinical research center, BioFortis, Inc.,⁶ maintains a database of people who have participated in clinical studies. BioFortis recruited and screened Participants in Chicago. In Cincinnati, Ohio, [REDACTED] were recruited and screened.

The Researchers anticipated that they were likely to attract Participants who were in the lower socioeconomic status given the areas from which they were recruiting, the health restrictions, and the goal of diverse racial and ethnic backgrounds as well as their experience with the Camp Calcium studies. The PI stated that it is known that high blood pressure in adults is linked to inability to access resources. That inability is associated with lower socioeconomic status.

Answers to Questions Posed by President Daniels

Camp Design

What programming and staffing were planned and implemented to ensure sufficient oversight and management of camp Participants? (Consider counselor-to-camper ratios; shift and schedule design; camp programs and activities; accommodations, and physical plant for camp activities.)

Staffing

Initially, the Researchers hoped to enroll 150 Participants for the first summer. The Researchers planned to have 70 to 80 Counselors (including Head Counselors).⁷ The plan was to have 1 Counselor to every 6 to 8 Participants. At the start of Session 1, seventy-eight Participants were enrolled,⁸ and 70 Counselors were on staff.⁹ The PI told the IRB, "At any one time, there are at least 16 counselors supervising the campers (1 to 4-5 ratio)."¹⁰ Simply stated, this was not true. Staffing was very light during the overnight hours. Usually, four Counselors were on duty overnight for as many as 78 Participants. This represents a ratio of approximately 1 to 20. However, there were nights when only three Counselors were on duty. That ratio is closer to 1 to 26.¹¹

The 79 Participants were divided by diet into four groups: A, B, C, and D. Each group was then divided into two groups: A1 & A2, B1 & B2, etc. Each of the smaller groups of about ten Participants had 2 Counselors assigned to that group for the two day shifts. While this appears to

⁶ BioFortis Clinical Research Center sources participants for clinical research studies. See <http://biofortisclinicaltrials.com/upcoming-trials.html>

⁷ This was based on staffing from Camp Calcium.

⁸ Another Participant joined the Study after the first week.

⁹ Dr. Weaver's June 20, 2017, memo to Biomedical IRB.

¹⁰ Dr. Weaver's June 20, 2017, memo to Biomedical IRB. Response to Question 8.

¹¹ Four overnight Counselors were scheduled to work. However, there were some occasions when there were only three Counselors for the overnight shift. At times, all three overnight Counselors were female.

be a one to five ratio, that was not always the case. At times, a Counselor would miss a shift. This would leave one Counselor responsible for ten Participants. At other times, one of the Counselors would be required to focus on one Participant who was lagging behind the group while walking somewhere on campus leaving the other Counselor to watch the other 9 or one Counselor would be preoccupied with one or 2 Participants who were exhibiting troublesome behavior.

Two Head Counselors were scheduled from 6:00 a.m. to 2:00 p.m. or 2:00 p.m. until 10:00 p.m. Head Counselors did not work overnight shifts. Some of the Head Counselors would stay until 11:30 p.m. Head Counselors confirmed that they often worked in excess of 40 hours per week and were paid at overtime rates. Two of the Head Counselors lived in Tarkington during the Study.¹²

Counselors worked two shifts: 7:00 a.m. until 3:30 p.m., and 3:00 p.m. until 11:30 p.m. Overnight Counselors worked from 11:30 p.m. to 7:30 a.m.

Several Counselors shared that having Participants from 11 years old to 15 years old in the same small group, i.e., A1 or B2, made it very difficult. The five year age span at that point in a child or young adolescent's life is significant from a developmental perspective. The Counselors reported that activities that interested the younger Participants did not interest the older Participants in the group and vice versa. The Head Counselors raised this issue during the planning stage (from January 2017 until roughly May 2017). They were told by the Researchers that the Participants would be assigned to their diet and thus their groups randomly, and it was necessary for the design of the Study. According to a member of the Researchers, this issue was discussed until very late in the planning for the summer of 2017.¹³ The Researchers had hoped that the older Participants would mentor the younger Participants.

They did not increase staffing for activities away from Tarkington.¹⁴

There did not appear to be backup plans in place for Participants who didn't want to participate in an activity. When these situations occurred, or when a Participant required special attention (i.e., a Participant not cooperating, needing to be escorted to another area, etc.) a Counselor would be diverted from supervision of the group. As a result, counselor to Participant ratios were insufficient and did not meet recommended standards published by the American Camp Association.

Two members of the research team, Dr. Martin and the doctoral student, were responsible for hiring staff for the summer of 2017. The model from Camp Calcium was loosely followed. Camp Calcium had one head counselor who was a graduate student or a senior college student

¹² Approximately sixteen Counselors lived in Tarkington on a separate floor from the Participants.

¹³ Witnesses reported that siblings and cousins were allowed to be roommates even if they were in another group. If this accommodation was made, it appears as though the research design might have allowed separation of Participants by age groups.

¹⁴ See Appendix, Exhibit 2, Incident Chronology for a description of incident regarding one male Participant burning another male Participant with sauna rock. This occurred in a male locker room. No male Counselors accompanied this group to the Co-rec which left the male Participants unsupervised while in the locker room.

with appropriate experience. They had planned to follow that model and provide an assistant to the head counselor. However, because the target number of Participants for Camp DASH was roughly twice that of the largest Camp Calcium,¹⁵ there was concern that two people could not manage the group. After reviewing applications, they found that six of the applicants had either extensive experience with Boiler Gold Rush or some camp experience. They decided to have a leadership team of six Head Counselors.

During the spring semester of 2017, the six Head Counselors met with Dr. Martin and the doctoral student every few weeks. One Head Counselor was charged with establishing a work schedule for the Counselors. Two of the Head Counselors were responsible for planning the training for the Counselors before the first session started.¹⁶ Other Head Counselors were tasked with planning activities for the Participants, planning special events such as parents' day, or recruiting the other Counselors.¹⁷

Accommodations

Tarkington. The Participants were housed in Tarkington Hall, a residence hall for male undergraduates. Tarkington is not air conditioned. The building is the shape of an "H" and consists of three stories. The residence hall rooms are along two long hallways with recesses that prevent line of sight from one end to the other. Male Participants were on one floor, and female Participants were on an adjacent floor. The area in the middle of the two perpendicular hallways includes common space such as the main desk and reception area. There are three stairwell exits and elevators on each of the main hallways. The basement has a TV lounge area and a somewhat isolated laundry room which is near the ice machine as well as a door that leads to a back stairway which leads to loading dock exit on the main floor. Participants quickly discovered that this area was not adequately monitored or supervised and that they could meet privately or exit the building without being observed by Counselors. During Session 1, Participants had swipe cards that allowed them access to their rooms during the day. Swipe card access was removed at the end of the first session to allow for more participation and supervision.

Cary Quad. Meals were served in the Cary Knight Spot Grill in Cary Quad, another residence hall for male undergraduates. Cary Hall is across Stadium Street from Tarkington Hall. The distance between Cary Quad and Tarkington is approximately 0.2 miles. Witnesses reported that Participants were often unsupervised, loud and used profane language on the trips between Tarkington and Cary.

¹⁵ The largest group of participants for any of the Camp Calcium studies was 85.

¹⁶ Those Head Counselors developed training for the other Head Counselors and Counselors but did not receive training. One noted that there was no review of the training materials by a University staff member.

¹⁷ We were informed that all but one applicant for a Counselor position was hired. That applicant was rejected because she did not seem interested in the job.

Stone Hall. Most measurements took place in Stone Hall, an academic building. The offices of the PI and other Researchers from the Nutrition Science department are in Stone Hall. Stone Hall is approximately 0.8 of a mile from Tarkington. This represents a 16 to 17 minute walk.¹⁸

Transportation

Researchers planned that Participants would walk to campus destinations. That proved difficult for some Participants. Several Participants refused to walk to other campus buildings. Walking around campus in their groups presented supervision issues.

When traveling off campus, University vans were used. Frequently, the driver was the only staff member in the vehicle. That led to at least two incidents. A post-doctoral researcher who was asked to drive on a field trip slapped a Participant on the leg. In another situation, the PI drove a van to and from a field trip. During the trip back to campus, a male Participant groped a female Participant against her will.

Programs and activities

While there was a detailed schedule for the measurements, the schedule for programming for Participants was lacking. Often, activities that appealed to younger campers did not interest the older Participants; the reverse was also true. At times, the scheduled activities did not take as long as the schedule allowed. And sometimes, there were hours of down time with nothing scheduled. This was particularly true during the evening hours. Large blocks of free time during the evening made supervision of the Participants even more difficult.

Administration of Medications

Participants arrived at check-in with prescription and over-the-counter medications that had not been previously disclosed during the screening process. Prior to the start of Session 1, a system to collect and record receipt of such medications was created by Dr. Martin who had a laboratory student employee who was licensed as a certified nurse aide¹⁹ and a nursing student make a chart and system for distribution of the prescription medications. However, there was a lack of communication of this system, and it was not clear who was responsible for inventory and distribution of the medications.

During the first few days of Session 1, prescription and over-the-counter medications were stored in an unsecured location. Only one secure, locking box had been available at the beginning of Session 1. Two additional locking boxes were purchased for storage of medications.

Some medications were dispensed to Participants by Counselors who did not possess medical training. As a result, these Participants were exposed to risks associated with misadministration of these medications and adulteration due to transport and storage in plastic bags.

¹⁸ This estimate is from Google maps.

¹⁹ The student had an active license during the entire period that Camp DASH was operational.

What controls were in place to address behavioral issues and ensure timely reporting of incidents?

At the beginning of Session 1, there was a code of conduct. Discipline included talking with the Participants, time outs, denial of participation in activity (which was not effective because often the child did not want to participate), and only in severe cases, were Participants dismissed from the Study. However, there was a tension between discipline and removing Participants with behavioral issues from the Study due to the PI's stated goal to retain the maximum number of research subjects for measurements. As a result, the Participants quickly understood that there were few or no consequences for inappropriate behavior. This contributed to additional inappropriate behavior as the camp continued. Witnesses indicated that Counselors felt "powerless" to impose effective discipline, to ensure the safety of the Participants and themselves, and for efficient functioning of the Study.

Timely reporting of incidents was haphazard and in most instances did not comply with University policies and procedures. There is also a question as to whether reporting in accordance with state statutes regarding suspected child abuse and neglect were satisfied. This report will not analyze this issue due to deference to law enforcement authorities.

The following policies and procedures were in place:

- Anti-Harassment (III.C.1)²⁰
- Campus Security and Crime Statistics (IV.A.2)²¹
- Background Checks (VI.F.6)²²
- Operating Procedures for Programs Involving Minors²³
- Guidelines of the University's Human Research Protection Program²⁴
- University Residences/Conferences requirements²⁵

Camp Compliance Culture

What measures were taken to establish expected standards of conduct for Participants?

²⁰ <http://www.purdue.edu/policies/ethics/iiic1.html>

²¹ <http://www.purdue.edu/policies/facilities-safety/iva2.html>

²² <http://www.purdue.edu/policies/human-resources/vif6.html>

²³ <http://www.purdue.edu/ethics/resources/programs-involving-minors.html>

²⁴ <https://www.irb.purdue.edu/guidelines/> The Unanticipated Problem and/or Adverse Event Report provides that, "Unanticipated problems and/or adverse events, whether they affect subjects or others, must be reported to the IRB. If the problem/event is either serious or unanticipated, complete this form and forward to the IRB Office. The problem/event must be reported to the IRB within 48 hours after the researcher first learns of the problem/event. This initial notification need not be in writing. However, within 5 business days, the Investigator must submit a written report with supporting documentation relevant to the report, if any. Changes in previously reported events or problems should be reported to the IRB Office. ..."

²⁵ <https://distance.purdue.edu/youthsafety/policies/hallsafety.aspx>

As part of the screening process, Participants were asked to provide two character references.²⁶ There was a code of conduct in place at the beginning of Session 1. A revised code of conduct was provided to parents/guardians and Participants during the break between the sessions.

Were camp personnel made aware of, and receive training on, working with youth and applicable reporting requirements?

During the training conducted before the beginning of Session 1, the Counselors received some training on working with youth. Many of the Counselors believed that the training was sufficient for their roles – until the Participants arrived, and they were confronted with much more serious behavior issues than expected. Staff did receive training regarding applicable reporting requirements of suspected child abuse and neglect. Some Counselors did not attend any of the training, and some attended only a portion of the training sessions. In accordance with the Study protocol and as part of their agreement with Conferences, all staff were required to complete one or more trainings on youth safety and reporting. The PI and the Camp Manager completed the online training regarding working with minors and reporting obligations.²⁷ As part of the registration of the camp portions of the Study, the Researchers certified that all staff had completed the required training.

As a part of the enhanced measures to permit the return of the Participants for Session 2 of the Study, the PI agreed that additional training would be conducted. The PUPD police made clear that they “would rather be inundated with potential crimes...than not know about them at all.” Staff were informed that they should report “everything that you think might be criminal activity” to the PUPD.

Were counselors made aware of the importance and availability of avenues to meet those reporting requirements?

Yes. The online training provides this information. The police provided this information at multiple points during the study including during the enhanced training conducted before the start of Session 2. Some Counselors reported that they did not complete all of the training.²⁸

Incident Reporting

Were all incidents that triggered a reporting requirement timely and properly reported?

No.

If not, why not?

Based upon the review of the available information, several factors contributed to this failure. There was confusion about what was required despite the training that was provided. Multiple, conflicting instructions were provided to Counselors.

²⁶ As part of the process of preparing this report, records from the Study were audited. Six of 79 Participants did not provide character references.

²⁷ Review of applicable records demonstrated that most staff had completed the required training.

²⁸ Following the training immediately before the start of Session 2, the training was available to Counselors online.

Counselors mistakenly believed that if they reported an incident to a Head Counselor, the Camp Manager or the PI, they had satisfied the obligation to report because they thought the proper authorities would be notified. The Head Counselors mistakenly believed that reporting to the PI, the Researchers, and/or the Camp Manager was sufficient.

In some cases, the PI, despite being informed of incidents, failed to report to PUPD, IRB, University Residences, and other authorities. In some cases, although the PI eventually reported the incident, such reports were not made in a timely manner. In the incident involving the video recording, the Head Counselor immediately emailed both the Camp Manager and the PI. He then called and spoke with the Camp Manager. The Camp Manager emailed the Head Counselor, copied the PI, confirmed receipt of the report and stated that he would contact the PUPD the next morning.

Institutional Response – Session 1

How did the University respond to reported behavioral issues during the first session of the study?

Summary of Behavioral Issues and Institutional Response—Session 1

Difficulties with the camp-related operations of the Study were apparent from the start of Session 1.²⁹ During the first week (June 10-17, 2017):

- Two Participants were arrested and dismissed from the Study in the first week. Both incidents involved violence among the Participants, and one Participant required transport to a hospital for treatment as a result of the violence.
- PUPD officers were dispatched to Tarkington Hall in response to Participant altercations on two additional occasions.

In response to concerns regarding Participant behavior and safety:

- A meeting was held on June 14, 2017 among Dr. Weaver, Dr. Martin, and representatives of PUPD, Environmental and Public Safety, and University Residences to discuss problems. Weaver agreed that “staff will immediately call PUPD if there is violence or threats made between Camp attendees.”
- “Protocols for Campers’ Safety” was distributed to Study Staff. Staff directed to “Contact police immediately for behaviors that constitute a crime against a person. This means touching a person in an angry, threatening manner or a sexual aggression. They would like to speak with those involved before it escalates into a felony.”³⁰
- An Incident Form was distributed to Study Staff with direction from Dr. Weaver to complete and forward to Dr. Weaver or Dr. Martin. “We will contact conferences as directed.” Incidents to be reported include “Violence including fights, Sexual Assaults or Harassment, Threats, Bullying, Weapons, Alcohol, Drugs, Police Involvement.”

²⁹ For a chronology of significant incidents involving the camp portion of the Study, see Appendix, Exhibit 2, Incident Chronology.

³⁰ See Appendix, Exhibit 3, Dr. Weaver’s June 14, 2017, memorandum to Camp DASH staff.

- Action items to improve safety were developed and distributed by Dr. Weaver. She was informed that the action items (and demonstrable follow through on those items) would be important to the preliminary decision whether to suspend the protocol in the interest of safety of the human subjects.
- Following receipt of Unanticipated Problem and/or Adverse Event Report relating to the two incidents that resulted in the arrests of Participants, representatives of the Biomedical and Social Sciences IRBs met to discuss problems with the Study.
- Biomedical IRB informed Dr. Weaver that the Study will be suspended “[i]f another event occurs prior to July 5, 2017.”

Notwithstanding the action items and the message from Dr. Weaver to the Study Staff that “[b]ecause of the problems we had at the beginning of camp, we are under a microscope at the University and need to tighten our ship,” problems continued. During the second week of Session 1 (June 18-24, 2017):

- Counselors learned of accusations of sexual harassment and inappropriate touching by a male Participant against several female Participants. A Head Counselor reported the matter to Dr. Weaver on June 20, 2017. Although the male Participant was dismissed from the Study on June 21, 2017, the allegations and dismissal were not reported to the IRB chair by Dr. Weaver until July 5, 2017.³¹ These allegations were not reported to PUPD until July 20, 2017.
- Multiple incidents of bullying, violent and profane behaviors involving several Participants took place. In one incident, while unsupervised in a sauna in the Co-Rec, a male Participant burned another male Participant on the back with a rock from the sauna. [REDACTED]
- A Counselor expressed concerns regarding her safety and the safety of Participants and Counselors to Dr. Weaver due to several violent incidents involving a Participant. Although a “safety plan” for the Participant had been shared with Dr. Weaver, she did not share it with Counselors or Study Staff who had direct contact with or responsibility for supervision of the Participant.

Incidents of bullying, fighting and intimidation continued during the period June 25-30, 2017.

- Counselors reported concerns about the disruptive and violent behaviors of a number of Participants, and asked that a male Participant be dismissed from the Study.
- A female Counselor was subjected to sexually offensive comments and harassment by a group of male Participants during a “sleep over” permitted by Dr. Weaver in contravention of University Residences’ regulations. The Counselor resigned, citing in her message to Dr. Weaver, among other things, sexual harassment by those Participants and concerns for her personal safety.

³¹ Dr. Weaver reported this series of incidents to the chair of the IRB by email on July 5, 2017. The IRB had previously informed Dr. Weaver that the Study would be suspended if another event occurred before July 5.

- PUPD officers were dispatched to Tarkington Hall in connection with a dispute between two female Participants and in connection with a male Participant who attempted to assault Counselors.

In response to these continued problems, on June 30, 2017, PUPD Chief Cox informed Dr. Howard Zelaznik, then Associate Vice President for Research (with copies to representatives of University Residences, the Co-Rec and the Office of Legal Counsel) that, “[i]t is now my position there is an imminent threat to the health and safety of the children attending camp DASH.... Based on the information documented in past incident, information that children are still being harmed or committing crimes ... and incidents are not being report [sic] to police and/or University Residences as mandated and this latest act of violence towards a camp counselor, I recommend camp DASH be cancelled and the campers sent home.”

What oversight or other enhancements were made in response to those issues? What decisions were made based on those enhancements?

During the period June 30-July 4, 2017, University administrators considered whether the camp portion of the Study ought to be suspended or terminated. Units represented included the Office of the Provost, Office of the Executive Vice President for Research and Partnerships, the College of Health and Human Sciences, the Department of Nutrition Science, the IRB, PUPD, University Residences, and the Office of Legal Counsel. In anticipation of a meeting to be held on July 3, 2017, and to which she was not invited, Dr. Weaver sent an email to Dr. Forman on July 2, 2017 that attempted to address “[w]hat interventions does the Camp propose to address and prevent problems such as those already encountered?”³² That email message was shared with the individuals at that meeting.

In response to the interventions and enhancements outlined in Dr. Weaver’s email, Chief Cox indicated that he could support continuing the camp if “[p]rogram management actually follows through on what they say they are going to do” and “[t]here is immediate reporting of behaviors that are illegal or violate university policy as they have been instructed in the past.” Chief Cox also stated that if “a camper commits another violent act against another camper, the program should be shut down immediately.” The PI pledged to report as directed by the Chief of the PUPD. The study was allowed to continue into the second session contingent upon the satisfaction of enhancements outlined by the PI in her email dated July 2, 2017.³³

On July 4, 2017, Dr. Akridge conveyed the University’s decision to permit the camp portion of the Study to continue, and that such decision was supported by the Chair of the Biomedical IRB. Unknown to Dr. Akridge and those involved in the decision to continue the camp portion of the Study, serious incidents involving sexual harassment and misconduct by a male Participant against several female Participants and violent actions of a male Participant against other Participants, including the incident that resulted in a second degree burn to a male Participant, had not been reported to anyone outside of the Study. Each of these events was known to Dr. Weaver, but not reported to the IRB until July 5, 2017. Significantly, the IRB informed Dr.

³² See Appendix, Exhibit 4, Dr. Connie Weaver’s email of July 2, 2017 to Dr. Michele Forman.

³³ See Appendix, Exhibit 4.

Weaver on June 17, 2017, that it would suspend the Study if another event occurred prior to July 5, 2017. Although Dr. Weaver reported the incidents to the IRB, she did not report these two matters to PUPD.³⁴

In her July 2, 2017 email message, Dr. Weaver represented for “every aspect of each incident Dr. Weaver has: engaged with counselors who were on sight (sic) when the event occurred; with the parents; and the police.” Dr. Weaver had not engaged with the police on every “incident.” She also represented that, “all medications are stored in a locked room with access only by the nurse and nursing student to prepare daily prescriptions” There was no nurse on staff at Camp DASH. A certified nurse aide and a nursing student performed these tasks. Dr. Weaver also represented that the “ratio of counselors to campers is no less than 1:4-5 24-7.” This was not accurate.

On the evening of July 4, 2017, Dr. Weaver and other staff drove Participants off campus to view fireworks. A female Participant, after returning to Tarkington Hall and speaking with her mother in the early hours of July 5, 2017, reported to a Counselor that a male Participant inappropriately touched her breasts and thighs during the return van ride to campus.³⁵ The Counselor reported the allegations to a Head Counselor, who in turn reported it to Dr. Weaver. Dr. Weaver declined to report it to PUPD or any other department. Notwithstanding Dr. Weaver’s decision not to report the incident, the Counselor completed both an incident report and a Campus Security Authority (“CSA”) Report with respect to the incident. A representative of PUPD had discussed the CSA reports earlier that day. PUPD did not immediately follow up on the CSA report.

On July 5, 2017, the Participants went home for the scheduled break between Session 1 and Session 2. Overall, seven Participants had been dismissed during Session 1, and one had volunteered to leave.

As part of the enhancements and plans discussed with University administrators, the PI sought and hired two individuals as Counselors who had experience working with inner city youth. Additionally, in accordance with the agreed upon interventions and enhancements outlined in Dr. Weaver’s July 2, 2017 email and as required by the IRB, a Camp Manager was hired. His employment commenced at the beginning of Session 2, on July 10, 2017.

Summary of Actions by Human Research Protection Program, Institutional Review Boards—Session 1

On June 15, 2017, Dr. Weaver submitted an Unanticipated Problem and/or Adverse Event Report [“URPITSO”] to the IRB. This followed a telephone call to Dr. Elliott, chair of the Biomedical Review Board to report the incident. In the email, she told him that she would send a second email with another report. The first report was regarding the June 13, 2017, assault of one Participant by another and the subsequent arrest of the assailant and removal from the Study. As she promised, also on June 15, Dr. Weaver submitted a second URPITSO concerning the

³⁴ Dr. Elliott, chair of the Biomedical IRB, attempted to report the incidents to PUPD both in person and by telephone. PUPD did not follow up with him.

³⁵ Dr. Weaver was the driver of the van.

assault by a Participant on another Participant on June 12, 2017. That assailant was also arrested and removed from the Study.

On June 15, 2017, members of both the Biomedical and Social Science Review Boards met to discuss the URPITSOs submitted by Dr. Weaver. In a follow up to that meeting, the Biomedical IRB wrote to Dr. Weaver on June 17, 2017. The IRB requested additional information from Dr. Weaver. Significantly, the IRB stated:

The IRB determined that if a similar incident described in the Unanticipated Problem and/or Adverse Event Reports occurs the IRB will suspend the data collection and analysis on the study. If another event happens prior to July 5, 2017 the camp will be suspended and if not corrected to the satisfaction of the IRB, the second visit (July 12, 2017-August 3, 2017) will be cancelled.

If a similar incident occurs between July 12, 2017 – August 3, 2017, the IRB chair will suspend the data collection and research component of the camp.³⁶

The IRB noted that a subcommittee would be formed to review information submitted by Dr. Weaver and report to the full IRB at their meeting on July 11, 2017. In addition to the two warnings noted above, the IRB also asked Dr. Weaver to submit additional information to supplement the reports of June 15. On June 20, 2017, Dr. Weaver provided additional information requested by the IRB. On June 26, 2017, Dr. Weaver provided URPITSOs with more detail regarding the two incidents.

Institutional Response – Session 2

Were the enhanced measures implemented during Session 1 followed in Session 2?

Some, but not all, of the enhanced measures were followed in Session 2, which commenced on July 11, 2017, when the Participants returned to campus. For example, the Camp Manager's employment began on July 10, 2017. Additional training was held for Counselors and Study Staff that included safety and reporting requirements and guidelines and topics addressed to Participant issues such as bullying, self-harm and how to behave in an orderly fashion.³⁷ In addition, regular stakeholder meetings were instituted. Notwithstanding the implementation of these measures, additional incidents of misconduct and disruptive behavior soon occurred during Session 2.

³⁶ In response to the warnings about further incidents, Dr. Weaver wrote the following to the IRB when she submitted the requested supplemental information: "I understand that if an assault occurs and a camper is injured, suspension may be necessary. However, I implore the committee to allow us to take emergency steps to remove a disruptive camper without fear of shutting down the study. I have conducted 11 previous summer research camps; this is the first time, ever, that incidents leading to arrests have occurred." Dr. Weaver's June 20, 2017, memo to Biomedical IRB.

³⁷ Notwithstanding the trainings, inconsistent direction provided by PUPD officers, the PI and the Camp Manager resulted in persistent confusion among Counselors about what should be reported by them directly to PUPD.

Summary of Additional Behavioral Issues and Institutional Response—Session 2

The following is a summary of those incidents³⁸ and actions taken in response to them.

- Upon discovering that their daughter may have engaged in consensual sexual activity with a male Participant, a female Participant was removed from the Study by her parents. The Participant's mother notified Dr. Weaver of the removal of their daughter, the reason for such removal, and the need for greater supervision of Participants.
- A Study Staff member reported that a Participant made improper advances toward her during a lab test.
- Two Participants were dismissed from the Study by the Camp Manager for "attitude issues." The Camp Manager believed that their behaviors detracted from the progress being made in improving Participant behavior.
- A Counselor, while allowing two female Participants to stay up with him past the scheduled bedtime, posted photographs on social media of them with their heads on his thighs, and he showed favoritism to them. Although the Camp Manager indicated that the Counselor's employment would be terminated for such misconduct, he did not do so, and did not report such misconduct to anyone outside the Study.
- A female Participant engaged in a series of sexually violent acts toward male Participants and attempted to choke a male Participant. This female Participant was dismissed from the Study on July 18 for fighting. That evening, Participants and Counselors reported that the female Participant who had left earlier that day posted a nude video of another female Participant on social media. The video was viewed by two male Participants. One of the Head Counselors reported the incident to the Camp Manager and Dr. Weaver that evening. Due to the hour, the Head Counselor followed up with a phone call to the Camp Manager that evening. The Camp Manager indicated that he would contact the police in the morning.

As was the case with many of the events that occurred in Session 1, many of these incidents were not reported to anyone outside of the Study.

PUPD received reports regarding the posting of the nude video on July 19, 2017. Later that day, details regarding the incident and his recommendation that the camp portion of the Study be shut down was conveyed by Chief Cox to Dr. Akridge, who agreed that the shutdown was necessary.

On July 20, 2017, Dr. Weaver was informed that the University was closing the camp portion of the Study because the Participants were not adequately supervised and protected.

Following notification of parents/guardians, the remaining 46 Participants were sent home on July 21, 2017.

³⁸ See Appendix, Exhibit 2 Incident Chronology.

*Summary of Actions by Human Research Protection Program, Institutional Review Boards—
Session 2*

On July 5, 2017, Dr. Zelaznik wrote to Dr. Weaver and copied Dr. Elliott. Dr. Zelaznik asked for information due to his need to file a report with the Office Human Research Protections of the NIH. Dr. Zelaznik also noted that he had heard that eight (8) Participants had been sent home and that the IRB needed to know if any of the dismissals were related to the protocol. Dr. Zelaznik asked Dr. Weaver to send the reports to Dr. Elliott and copy him.

Later that evening, July 5, 2017 at 8:32 p.m., Dr. Weaver sent an email to Dr. Elliott,³⁹ chair of the Biomedical Review Board, with a copy to Dr. Zelaznik. The email attached hand written notes from Participants regarding the sexual harassment of several other Participants⁴⁰ and incident reports regarding three other Participants who were dismissed from the Study. The next morning, Dr. Weaver complied with Dr. Zelaznik's request and again wrote to Dr. Elliott and copied Dr. Zelaznik. She noted that as of Thursday, July 6, seven Participants had been dismissed and one volunteered to leave. In that email, she noted that the incident report forms had been shared with conferences and had included the names of the Participants. She asked if the names should be replaced with research subject numbers.

Following receipt of the emails from Dr. Weaver, Dr. Elliott asked that Dr. Weaver send the reports on URPITSO forms. On July 7, 2017, Dr. Weaver sent the URPITSO forms.⁴¹ She also provided a brief update. Dr. Weaver noted her ongoing efforts manage the issues, meetings with various University stakeholders, seeking additional help from "Psychological Services," and the hiring of a Camp Manager. She noted that they had finished Session 1 with 63 Participants, and that the Participants had returned home for the break between to two sessions.

On July 11, 2017, the IRB suspended the Study effective July 11, 2017.

On July 14, 2017, the IRB approved the amendment to the protocol and removed the suspension of the protocol. This was informally communicated to Dr. Weaver and followed with a formal communication on July 26, 2017.

On July 21, 2017, Dr. Weaver submitted two URPITSO forms. One reported the video recording of one female Participant while nude by another female Participant⁴² and the subsequent sharing of the video on social media and with other Participants. The other URPITSO reported a breach of the confidentiality of the Participants due to the sharing of all Participants' contact information and Study identification numbers with the PUPD in connection

³⁹ See footnote 34.

⁴⁰ See Appendix, Exhibit 2 regarding incidents that were reported to Dr. Weaver on June 20, 2017. The Participant was dismissed by Dr. Weaver on June 21, 2017.

⁴¹ The four incident reports involved three incidents that occurred on June 30, 2017. PUPD was not called in two of the incidents. PUPD was notified of one of the three incidents, but no arrests were made. The other incident occurred on June 21, 2017.

⁴² See Appendix, Exhibit 2

with multiple police investigations.⁴³ It is not clear that reporting such information to the police in connection with its investigation is a violation of confidentiality.

On July 24, 2017, consistent with the IRB's previous communications with Dr. Weaver, the IRB changed the status of the Study protocol to Data Analysis Only. This was communicated informally to Dr. Weaver by Dr. Elliott in an email dated July 25, 2017, and formally on July 26, 2017.

How could the University's response to behavioral issues reported during the second session have been improved?

Incidents of suspected child abuse, including the incident of sexual exploitation⁴⁴ of one Participant by another⁴⁵ should have been reported to the PUPD immediately as the PUPD had instructed during the training session held before the start of Session 2.

The incident that precipitated the ultimate decision to close the camp was reported to the Camp Manager between 10 and 11 p.m. on Tuesday, July 18, 2017. A Head Counselor sent an email to the Camp Manager and the PI, and due to concern that the Camp Manager might be asleep, the Head Counselor then called the Camp Manager and discussed the incident. The Camp Manager confirmed his conversation with the Head Counselor by email within 30 minutes of the initial email and stated that he would report it to PUPD the next morning.

The University administration made the decision to close the study and send the Participants home within 24 hours of the matter being reported to PUPD. The University administration did not learn of multiple other incidents that occurred during Session 1 and during Session 2 until after the Study was stopped.

Additional Observations and Concerns Regarding the Camp Dash Study

Budget

According to the PI, grant proposals to NIH typically have a \$500,000 per year limit on direct costs. She knew that the Study would cost significantly more than that. She had to obtain permission from NIH to submit a grant proposal in excess of \$500,000 per year. She submitted a budget for the Study in 2011 or 2012. The budget for the Study was locked in at that time. By the time the Study was funded and planning for the summer of 2017 began, the Researchers knew that the budget was tight due to increased costs for salaries and supplies since the time she submitted the initial budget.

⁴³ The IRB noted that, "If there are any further study camps a new protocol with appropriate safeguards will need to be submitted."

⁴⁴ Under the University policy on Anti-Harassment, the term Sexual Exploitation is defined to include, "An act that exploits someone sexually. Examples of Sexual Exploitation include, but are not limited to: . . . Recording video or audio, photographing, disseminating, or transmitting intimate or sexual utterances, sounds or images without Consent of all parties involved."

⁴⁵ A female Participant used her phone to make a video recording of another female Participant while she was nude shortly before showering. The Participant who made the video recording then showed it to some male Participants and shared it via social media with others.

This led to an environment of cutting costs wherever possible.⁴⁶ The PI stated that she solicited donations of approximately \$50,000 of food to be consumed by the Participants.⁴⁷ When planning called for 150 campers, a non-air conditioned residence hall was selected to house the Participants during the 2017 summer. This resulted in a savings of \$25,000 by foregoing air conditioning for the Participants.

During Camp Calcium, there had been a lab manager to supervise the students working in the lab to process the measurements from the campers. However, the lab manager retired before the beginning of the Study, and she was not replaced. During Camp DASH, the responsibility of managing the lab fell to Dr. Martin.⁴⁸ This gave Dr. Martin less time to be involved in onsite supervision than she had during the Camp Calcium studies. While it is not clear that the lack of funding was the reason a lab manager was not hired after the previous lab manager retired, it is a reasonable conclusion to be drawn.

Due to the demands of running the Study, the onsite core members of the research team, Dr. Weaver, Dr. Martin, and one of Dr. Weaver's doctoral students, worked extremely long hours. One witness estimated that they were getting no more than three to four hours of sleep per night while the Participants were on campus.

The tight budget may also be the explanation for the PI's involvement in driving Participants on field trips.

Head Counselors were paid \$15.00 per hour and counselors earned \$9.50 per hour. Although the Counselor to Participant ratio did not meet guidelines established by American Camp Association,⁴⁹ payments to Counselor staff was over budget according to the Researchers.

The tight budget may have influenced the failure to have appropriately trained and licensed medical staff.⁵⁰

Staff Qualifications and Training

As noted earlier, although it is a research study, the Study was represented and marketed to parents/guardians and Participants as a residential camp "similar to a 4-H or sports camp." The general public expects, and camping industry standards require, that a summer camp be overseen by a qualified camp manager. As discussed previously, although Drs. Weaver and Martin had

⁴⁶ Initially, insurance to cover medical expenses for Participants was not purchased. A staff member attributed that decision to the cost of the insurance which was estimated to be \$0.45 per Participant per day. After the first week the Participants were on campus, this was brought to Dr. Weaver's attention, and she authorized the retroactive purchase of the insurance.

⁴⁷ This included a semi truck load of Aquafina bottled water from PepsiCo, and A2 milk which was the subject of one of the Study's ancillary studies.

⁴⁸ There were two shifts of lab workers. The first shift started early in the morning around 6:00 a.m. or 7:00 a.m. They would work until just after lunch. The next shift of lab workers started work in the mid-afternoon and into the evening. There were six to eight lab staff on each shift. Dr. Martin believed that she needed to be on site at the lab for shift changes. The lab management tasks led to Dr. Martin being on site at Tarkington less time than she had been for the Camp Calcium studies.

⁴⁹ See American Camp Association Standard HR.8.1

⁵⁰ See *infra* Deviations from Consent Form Approved by IRB and Deviations from IRB Approved Protocol.

experience with Camp Calcium and some Counselors had previously served as counselors in a residential or day camp, no one on the Study Staff possessed the requisite background and expertise to manage a residential camp. A Camp Manager with experience in a school corporation, in operating a community center serving children from low socio-economic backgrounds and managing a residential treatment facility for youth was hired for the Second Session.

Although most Study Staff received some training on reporting suspected child abuse and neglect, little education or training was provided with respect to child and adolescent development or behavior until shortly before the start of Session 2. They also received insufficient training to equip them to interact successfully with children with special needs and/or from disadvantaged backgrounds. Most Counselors and Head Counselors who were interviewed said that they felt unprepared for the challenges presented by the Participants.⁵¹ At least one Counselor indicated that they did not receive any of the in person training provided to Counselors during orientation. A link to video of the training offered prior to Session 2 was made available to Counselors who missed all or a portion of that training.

Despite ready access to experts within the College of Education, the College of Agriculture and the College of Health and Human Sciences, no outreach to those experts was made in responding to the mounting behavioral issues among some of the Participants or the clear deficiencies in the camp aspects of the Study. Assistance from the Clinic operated by the Department of Psychological Sciences was requested and provided to address the needs of one Participant.

In order to ensure that all Study Staff having contact with Participants understood the rights and protections afforded to human research subjects, and in accordance with the Study protocol, all Study Staff were to complete CITI Training. A review of the records indicates that such training was not completed by all Study Staff, notwithstanding the statement from the IRB to the PI to that effect during its review in connection with its suspension of the Study protocol. Nearly 13% of the Counselors failed to complete the training. Particularly troubling is the fact that the Camp Manager (identified as a Key Personnel in the Study protocol) failed to complete any CITI training until July 20 (the day he was terminated and 10 days after he began his employment with the Study) and that he did not complete the training designed for Key Personnel. Significantly, and as a result, he did not complete the module on "Vulnerable Subjects – Research Involving Children."

In accordance with the Study protocol, the Study was required to comply with Purdue's Youth Safety Program. As a result, an authorized representative of the Study completed a Programs for Minors Registration Form for each Session. That form included written certification that at the start of Session 1 and Session 2 of the Study, "all Program Staff have completed training on Youth Safety and Mandatory Reporting in Indiana within the 24 month period preceding the start

⁵¹ Several of the Counselors and Head Counselors reported being stressed and distressed by their work. Many of the Counselors quit despite the relatively high hourly rate paid to the Counselors and Head Counselors.

of the program.” A review of records indicates that, as with the case of CITI Training, not all Study Staff completed this training.

Conflicts of Interest of PI and Others

The PI had a conflict of interest when making decisions about incident reporting and dismissal of Participants from the Study. As noted in earlier sections of this report, the original enrollment goal for Participants for summer 2017 was 150. Multiple witnesses reported the perception that the PI expected to control dismissal decisions because of the need to retain a sufficient enrollment level for the power calculation.

The IRB addressed this inherent conflict of interest when they required the PI to hire a Camp Manager before the second session with “authority to terminate participation of subjects independently of the Principal Investigator.”⁵²

This conflict of interest may have contributed to the delay in reporting of some incidents and the outright failure to report other incidents.⁵³

Additionally, this conflict of interest likely influenced the decision to retain a Participant who required support from a child and adolescent psychologist [REDACTED]. This topic was addressed by the IRB in the 7-21-2017 modification of the protocol.

Concern was expressed by one witness of a potential conflict of interest on the part of the department head in Nutrition Science due to the fact that she had some oversight responsibility for the Study and had submitted a grant proposal that would be an additional ancillary study that would use future Camp DASH Participants as research subjects and provide additional funding. However, the department head disclosed her submission to the University administrators⁵⁴ who made the decision to allow the Study to continue. The disclosure was contained in an email dated July 3, 2017 at 5:05 p.m. The decision to allow the Study to continue was made on July 4, 2017.

Institutional Conflicts of Interest

Institutional conflicts of interest may also have played a role in the problems that developed during the Study and the response to those problems.

The Study was primarily funded by an \$8.8 million grant from the NIH. The grant, payable over a five year period, represents a significant sponsored program grant within the Department of Nutrition Sciences and the College of Health and Human Sciences. Both the size and importance of the grant were well known to University departments and personnel who had contact with the Study and its Participants. Dr. Weaver, a Distinguished Professor and former Department Head, is highly regarded and well respected both at Purdue and within the discipline. Faculty, post-

⁵² IRB Approved Protocol for the Study, Revision 7-21-2017.

⁵³ See Appendix, Exhibit 2

⁵⁴ Dr. Michele Forman's email was addressed to Trenten Klingerman, Jay Akridge, Suresh Garimella, Howard Zelaznik, Stephen Elliott, Christine Ladisch, and Beth McCuskey. The email is included in the Appendix as Exhibit 5 (“Thus all of us who are resubmitting will pause if not decline to resubmit if the study is stopped.”).

doctoral and graduate researchers, both internal and external to Purdue, wished to perform additional, ancillary research studies on the Participants.

Information obtained during our investigation indicated deference to the PI and the Study in a number of areas, including:

- the manner in which the Study was reviewed and approved by the IRB, (e.g., reliance on “expertise” acquired from the Camp Calcium studies and the presence of Dr. Martin, a member of the Biomedical Review Board, at its meeting with Dr. Weaver);
- the decision to permit the Participants to be housed in University Residences (despite negative experiences with Camp Calcium) and its decisions not to enforce its rules (e.g., reporting of certain events and prohibitions on changing room assignments);
- the solicitation and acceptance of certain gifts-in-kind by food vendors (including a gift prohibited by contract); and
- allowing the Study to continue after the arrests during the first week of Session 1 in reliance at least in part upon Dr. Weaver’s reputation

In addition, at least one administrator expressed concerns about the impact of closing the Study on relationships with NIH. A number of witnesses also expressed grave concerns regarding the possible negative impact on their academic futures of actions or opinions that could be perceived by Dr. Weaver as disagreeing with her opinions or desires. Nonetheless, and to their credit, a number of Counselors, concerned about the safety and welfare of the Participants and Study Staff, utilized confidential reporting mechanisms to share their concerns or resigned in spite of the financial hardship associated with that decision.

Deviations from Consent Form Approved by the IRB

Supervision

The Parent or Guardian Consent Form that was approved with the final approved protocol (05-21-2017) that was in place when Participants arrived for Session 1 stated, “Your child will live in housing provided by Purdue University for two 25 day study periods. **They will be supervised at all times.**”

They were not.

Witnesses reported the following:

- Seeing Participants walk between Tarkington Hall and Cary Quad without counselors.
- Seeing Participants at the fountain on the Engineering Mall at night without counselors or other adults.
- Male Participants were taken to the Co-rec by female counselors. Male Participants went to the men’s changing room near the swimming pool. One Participant used a towel to pick up a sauna rock and burn the lower back of another Participant causing a second degree burn.
- A male Participant and a female Participant met in or near the laundry room to engage in sexual activity.

- A male Participant groped a female Participant in a van while returning to Tarkington Hall from a field trip. The PI was the only staff member present, and she was occupied with driving.
- In responses to the survey of parents, there were reports of unsupervised Participants going to a nearby McDonald's restaurant without permission.

Misrepresentations regarding credentials of Camp Staff

The Parent or Guardian Consent Form which was approved with the final approved protocol that was in place when Participants arrived (05-21-2017), stated, "The camp staff will include Indiana licensed paramedics or registered nurses who are available at all times to handle any medical emergencies that may arise."

There were no licensed paramedics or registered nurses on the camp staff. The PI stated that one staff member is a registered nurse. She is not.⁵⁵ The staff member had been licensed as an "EMT – Basic" for one year from 1996 until 1997. The staff member reported that at various times before becoming employed at Purdue in 2004, she had been a certified nursing assistant, a qualified medication assistant, and a certified phlebotomist. The staff member stated that she does not have any current medical-related certifications or licenses.

Deviations from the IRB Approved Protocol

The protocol that was in place when the first session of the Study started on June 10, 2017, had been approved by the IRB on May 21, 2017. Under the heading, "Potential Risks to Subjects" the following text appears:

In order to provide maximum safety and security for the Participants, all staff involved in the study including live-in and daytime counselors, medical staff, kitchen staff, and laboratory staff will undergo an intense training and orientation session (3-5 days). Major topics include orientation to all research intervention techniques, safety and emergency guidelines by police and fire staff, diversity sensitivity training, behavior management training, CITI training, vehicle transportation training, blood borne pathogen training for lab staff, sanitation and food safety training for kitchen staff, basic first aid training. All personnel involved with the camp will undergo necessary background checks.

Resources to handle medical emergencies include an Indiana Licenses registered nurse (MSN) on staff that is available at all times, and a university fire department operating 2 ALS ambulances at all times. There will always be someone (counselor, staff) on duty with CPR training. . . .

⁵⁵ When asked if anyone in the Nutrition Science department referred to her as a nurse, the staff member stated that the PI did, but that she corrected her every time.

None of the witnesses described the training which preceded Session 1 as “intense.”⁵⁶ Further, none of the Counselors interviewed believed they were sufficiently trained for the behaviors of the Participants that they encountered. Some witnesses stated that they missed some or all of the training for Counselors.

CITI training is a reference to educational courses provided by the Collaborative Institutional Training Initiative. According to its website,⁵⁷ the program is “dedicated to promoting the public’s trust in the research enterprise by providing high-quality, peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics pertinent to the interests of member organizations and individual learners.”⁵⁸ Purdue University is a member organization.

“Purdue University requires all individuals engaged in the conduct of human subject research to have current CITI certification”⁵⁹ The CITI Human Subjects Research Basic Course takes about 2 to 4 hours to complete. An audit conducted of the staff of the Study determined that 15 staff members did not have current CITI certification as required both by the approved protocol and Purdue’s Human Research Protection Program.

According to University records, background checks were completed for only seven of 132 people on the staff list for the Study.⁶⁰

As noted above, there was no registered nurse on staff. The PUFD does maintain 2 advanced life support [“ALS”] ambulances capable of transporting patients to the two hospitals in Lafayette.⁶¹ PUFD also has a state-certified ALS engines. It is not a transport vehicle, but it is equipped with all appropriate ALS response equipment. On each of three 24 hour shifts, there are at least seven and as many as 9 firefighters on duty 365 days per year. Each PUFD firefighter is either an EMT or paramedic.

It was not possible to audit whether there was “someone (counselor, staff) on duty with CPR training.” Although the Researchers were able to provide sign in sheets for CPR training that was conducted at the beginning of the second session, the sign in sheets from the first session

⁵⁶ Additional training for counselors was conducted before the second session.

⁵⁷ <https://about.citiprogram.org/en/mission-and-history/> accessed September 17, 2017.

⁵⁸ CITI Program Mission Statement.

⁵⁹ <https://www.irb.purdue.edu/training/required-training.php> accessed September 17, 2017.

⁶⁰ For more than a decade, as part of its efforts to provide a safe campus, the University routinely and regularly screens all enrolled Purdue students and all employees against the Sex Offender Registry for violent offenders (murder and manslaughter), sexually violent predators (rape, criminal deviate conduct, child molesting, vicarious sexual gratification), offender against children (child molesting, child exploitation, child solicitation, child seduction, kidnapping (non-parental), and sex offender (sexual misconduct with a minor, sexual battery, incest, possession of child pornography, vicarious sexual gratification, sexual conduct in presence of a minor, criminal confinement (non-parental), promoting prostitution, human trafficking, promotion of human trafficking, sexual trafficking of a minor. No Purdue University West Lafayette students, faculty or staff have been on the Sex Offender Registry in 2017. Most of the staff for Camp DASH were West Lafayette students, faculty, and staff. During our review, we took the added step of checking the national sex offender registry and confirming that Camp DASH staff who were not Purdue students, faculty or staff were not listed on the registry.

⁶¹ If both ambulances are unavailable, Purdue Dispatch will contact the Tippecanoe County Emergency Ambulance Service [“TEAS”]. The University has a written mutual aid agreement with TEAS.

had been discarded. Additionally, because of changes to the work schedule for counselors, it is not possible to determine when each counselor worked.

Before the second session, the IRB required an amendment to the protocol that included extensive modifications of the safety and security paragraph. None of the provisions of the protocol listed above were amended with the July 21, 2017 version of the protocol for the Study.

Under the heading, "Investigator's Evaluation of the Risk-Benefit Ratio" of the May 21, 2017, IRB approved protocol, the following representations were made:

The risks to the individual are not great. Health professional (sic) will use sterile technique to reduce any risk of infection from medical procedures. Multiple steps to ensure safety and security have been outlined in the Section G [Potential Risks to Subject] above.

This paragraph was not changed in the 7-21-2017 version of the protocol. There was no one on staff who could accurately be described as a "health professional." As detailed above, many of the steps outlined in the protocol as steps to ensure safety and security were not completed.

Blood Pressure Measurement Training

[REDACTED]

[REDACTED] The staff member who trained the lab staff to take blood pressure measurements of the Participants is not a certified nurse.⁶² Although the protocol for the Study was modified for the start of the second session, this section was not corrected. [REDACTED]

Data Collection after Study Closed and IRB changed status to Data Analysis Only

On Thursday, July 20, 2017, the University Administration ordered that the Study be stopped and all campers sent home on Friday, July 21. The IRB directed that the protocol for the Study be changed from Data Collect to Data Analysis Only effective Monday, July 24, 2017.⁶⁴

Measurements were collected from four Participants after the Study was ordered closed. The PI allowed one Participant to take food home, leave campus, and remain part of the study. This

⁶² The staff member who conducted the blood pressure training is the same staff member who was licensed as an EMT for one year.

⁶⁴ On July 25, 2017, Dr. Elliott emailed Dr. Weaver regarding details of communications with NIH. He noted that the IRB had changed the status of the Study to Data Analysis Only. Later that day, Dr. Weaver replied to Dr. Elliott's email and noted that measurements had been collected from two Participants that day. She noted that a university lawyer had approved bringing the Participants back to campus for collection of additional data. However, Dr. Elliott and legal counsel had been aware of only one Participant who returned to campus on Friday, July 21, after the other Participants had been sent home. The shift to Data Analysis Only was formally communicated by the IRB on July 26, 2017.

Participant and her mother returned to campus on July 21. This Participant's blood pressure was taken and a blood draw was also taken.

The PI gave another Participant permission to leave campus but stay in the dietary portion of the Study. She returned to campus on July 22 for a blood draw and to have her blood pressure taken.

The PI gave two other Participants permission to leave campus and remain on the dietary portion of the Study. In addition to the main part of the Study, these two Participants were also involved in an ancillary study. Each of the Participants returned to campus on July 25, and submitted to the following measurements: blood pressure, blood draw, and hydrogen breath tests (this last test required the two Participants to remain on campus for five hours).

Conclusions and Recommendations

In order to address the problems and concerns identified in the course of the review and assessment of the University's actions in connection with the Camp Dash Study (and reflecting the principles identified as guiding this review and assessment), I recommend that the University consider the following:

The Study

In light of (1) the severity of the harms suffered by some of the Participants; (2) the multiple failures to comply with University policies and procedures; (3) the multiple deviations from the Study protocol; (4) the failure to fully implement the steps outlined in the action items developed and distributed by the PI on June 15, 2017; (5) the failure to fully implement the enhancements outlined by the PI in her email dated July 2, 2017; (6) the failure to report in a timely fashion the existence of the nude video of a Participant that was posted on social media by another Participant in accordance with University policies and procedures; (7) the failure to comply with the conditions for the continuation of the camp portion of the Study imposed by the Provost on July 4, 2017; and (8) the collection of data from Participants after (a) the decision to close the camp portion of the Study as of July 21, 2017 which decision was communicated to the PI during a meeting on July 20, 2017 and (b) the status of the Study was changed to Data Analysis Only by the IRB, effective July 24, 2017, the University should consider:

- Whether, consistent with standard IRB procedures, any or all of the data collected in the Study may be used by the PI and Researchers;
- whether the University ought to permit the camp portion of the Study to resume, and if so, under what conditions; and
- imposing appropriate remediation and/or sanctions for individuals whose action or inaction contributed to the harm suffered by Participants, Counselors and Study staff.

Reporting

In response to the Participant behavior issues and other problems associated with Camp DASH, the University attempted to oversee camp operations primarily through incident reporting. To facilitate and supplement this reporting, regular meetings of University stakeholders were

required and were held. These meetings were not effective because of the failure to report incidents and/or the delay in reporting incidents.

In light of the failures to report in a timely fashion or to act in a prompt manner on reports of violations of University policies, injuries to Participants and/or suspected child abuse, the University should consider whether any of its policies or procedures need to be revised. It should also consider whether enhanced education ought to be developed for University staff who will serve as counselors or leaders of summer camps for minors.

Because these failures put all of the Participants, Counselors and Study staff at risk and resulted in emotional or physical harm to some of them, the University should consider whether employees who failed to follow University policies and procedures regarding reporting of these incidents should be required to complete remedial education and/or be disciplined for such noncompliance.

Budget

In the event that the University permits the resumption of the camp portion of the Study, the University should consider whether the budget is adequate to ensure the safety and welfare of the Participants.

Study Protocol

In the event that the University permits the resumption of the camp portion of the Study, the IRB should consider:

- whether enhancements to its procedures are required to ensure that all Key Personnel have completed required training prior to approval of a research protocol, or any amendment thereto;
- whether any action ought to be taken regarding the Study and the data collected in light of deviations from the Study's approved protocol;
- whether the information regarding potential risks to subjects in the Study protocol should identify additional risks associated with residential camping, including the risk of injury or harm that might be inflicted by other Participants. The Application Narrative in Study protocol of July 12, 2017, identifies only the "potential for breach of confidentiality" and Item 15 of the Participant Assent notes merely that "Because you will be living with other campers and be supervised by counselors, you may see or be part of a conflict that makes you feel bad or frightened"; and
- whether the Study should be reviewed and overseen by an external IRB, not connected to any of the PIs, Co-PIs or Key Personnel.

Camp Operations and Management

The University should review and consider adoption of standards established by the American Camp Association, the Camp Nursing Association and the Higher Education Protection Network in order to implement best practices to ensure the safety and wellbeing of Participants in the Study and in every University program and camp that hosts minors.

The University should establish a standing committee to undertake an annual review of risks associated with camps hosted by or at the University, and to make recommendations for necessary revisions to policies and practices.

The University should consider the creation of a position whose responsibility will be to oversee compliance by youth programs with University policies and practices relating to youth safety and reporting. Such individual would be expected to be on call and generally available for consultation during the period May 1 to August 15. The Ohio State University provides a model for the utilization of such position, including unified incident reporting.

Staff Qualifications and Training

The University should consider enhancing the resources available to educate and train University staff who are employed or serve as volunteers for youth programs.

In the event that the University permits the resumption of the camp portion of the Study, the University should consider:

- the adequacy of Camp Manager, Head Counselor and Counsel position descriptions, and required background and experience.
- taking appropriate steps to ensure that the staffing is sufficient and that the appropriate Counselor to Participant ratio (i.e. Counselors on duty to Participants present) is in effect depending on the nature of the activity and the needs of the Participants
- enhancing the training provided to staff (a) to better prepare them for the situations they may encounter, including training to address the needs of children whose needs (i.e., dietary, developmental) may require additional awareness, knowledge and skills, and (b) to empower them to take actions to protect the safety of Participants and staff.

Transportation of minors

The University should consider enhancing the training afforded to van drivers to address passenger behavior.

Health and wellness

The University should consider providing a designated healthcare provider on site to serve participants in University hosted or sponsored camps and programs for youth during the summer. Groups and programs could be assessed a fee for such service.

The University should consider adopting and mandating protocols for the distribution of medications to minors, collection of camper health histories, initial screening for communicable diseases, communication to appropriate staff of special needs, and record keeping.

In the event that the University permits the resumption of the camp portion of the Study, the University should consider:

- requiring the hiring of a registered nurse who will oversee the development and implementation of protocols for the distribution of medications to minors, collection of

camper health histories (including ensuring that inoculations are up to date), initial screening for communicable diseases, communication to appropriate staff of special needs, and record keeping;

- the adequacy of the residential and dining facilities for Participants. Although our undergraduate students may be comfortable in rooms without air conditioning, they are advised to bring personal fans and are adults who can better control ventilation and temperature. In addition, they are not also undergoing the dietary restrictions and other conditions of the Study. The Participants would have benefitted from closer proximity both to their dining facilities and to Stone Hall, the site where many of the measurements were taken; and
- the adequacy of restrooms, including increasing the frequency of their cleaning, in light of the ages of the Participants and the requirement that they collect samples of their urine and feces.

Supervision

In the event that the University permits the resumption of the camp portion of the Study, the University should consider:

- enhancing the training of staff to clarify what “supervision” means in a given situation, to anticipate problems and to separate Participants as needed ;
- establish behavioral expectations of Counselors and Study staff to address use of cell phones while on duty and posting of and communication with Participants on social media;
- limiting unscheduled and “free time” and ensuring that they are supervised;
- ensuring that on duty Counselors have immediate access to Participant rooms;
- develop protocols to ensure that Participants do not use facilities that are not suitable for them due to their age or maturity; and
- develop practices and protocols to ensure that activities in locker rooms and communal showering areas are adequately supervised.

Conduct of Participants

Prior to resumption of the camp portion of the Study, the University should consider:

- enhancing the Participant Code of Conduct;
- establish appropriate limitations on the use of cell phones and electronic equipment, including prohibitions of such use in restrooms, locker rooms and changing rooms;
- establish rules regarding posting on social media; and
- consulting with subject matter experts on the implementation of discipline and positive reinforcement techniques.

Conflicts of Interest

The University should develop and enhance existing education and training for research personnel, including education and training specifically targeted to undergraduate and graduate students, to resist pressures that may harm human subjects.

The University should take steps to communicate to all persons who provided information in connection with this review and assessment, including all Counselors and Study staff, the University's prohibitions on retaliation.

References

American Camp Association, Accreditation Standards for Camp Programs and Services (2012 Edition)

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979)

Arthur J. Gallagher & Co., Managing the Risk of Minors on Campus (2012)

Best Practices for Hosting Youth Camps on Campus, Marsh Risk Consulting, June 2005

Franke, Ann H. and Goldschmidt, Scott Z., Managing Camp Liability, NACUA Notes, Vol. 15, No. 3 (February 10, 2017)

APPENDIX

- EXHIBIT 1** Memorandum dated July 27, 2017, from Mitchell E. Daniels, Jr. to Alysa Christmas Rollock
- EXHIBIT 2** Incident Chronology
- EXHIBIT 3** Dr. Connie Weaver's memorandum of June 14, 2017 to Camp DASH staff
- EXHIBIT 4** Dr. Connie Weaver's email of July 2, 2017 to Michele Forman
- EXHIBIT 5** Dr. Michele Forman's email of July 3, 2017 addressed to Trenten Klingerman, Jay Akridge, Suresh Garimella, Howard Zelaznik, Stephen Elliott, Christine Ladisch, and Beth McCuskey

MEMORANDUM

To: Alysa Christmas Rollock, Vice President for Ethics & Compliance
From: Mitchell E. Daniels, Jr., President *Mitch*
Cc: Steve Schultz, Legal Counsel Trent Klingerman, Assistant Legal Counsel
Re: Camp DASH 2017
Date: July 27, 2017

By this memo I am authorizing and instructing you to lead an institutional review and assessment of the University's actions in connection with Camp DASH 2017 and to prepare a report, for public release, of your conclusions and recommendations.

Your work should review and assess responsive information on the following topics and questions, together with any related issues that appear pertinent to your final assessment:

Camp Design

1. What programming and staffing were planned and implemented to ensure sufficient oversight and management of camp participants? (Consider counselor-to-camper ratios; shift and schedule design; camp programs and activities; accommodations, and physical plant for camp activities.)
2. What controls were in place to address behavioral issues and ensure timely reporting of incidents?

Camp Compliance Culture

1. What measures were taken to establish expected standards of conduct for participants?
2. Were camp personnel made aware of, and receive training on, working with youth and applicable reporting requirements?
3. Were counselors made aware of the importance and availability of avenues to meet those reporting requirements?

Incident Reporting

1. Were all incidents that triggered a reporting requirement timely and properly reported?
2. If not, why not?

Institutional Response--Session 1

1. How did the University respond to reported behavioral issues during the first session of the study?
2. What oversight or other enhancements were made in response to those issues?
3. What decisions were made based on those enhancements?

Institutional Response--Session 2

1. Were the enhanced measures implemented during Session 1 followed in Session 2?
2. How could the University's response to behavioral issues reported during the second session have been improved?

Your work should move forward in a way that does not impede the current ongoing law enforcement investigation. Questions about the scope and methods for conducting the review should be directed to the Office of Legal Counsel, which may provide advice and/or arrange for additional resources to be made available to you to accomplish these objectives expeditiously.

Incident Chronology

Date of Incident	Reporting	Nature of Incident	Description of Incident
6/12/17	On 6/14/17, information provided to PUPD during investigation of another matter. Head Counselor 2 made internal report on 6/17/17. Dr. Weaver reported to IRB on 6/15/17.	Assault	A Participant attempted to choke another Participant. Participant arrested and dismissed from the Study.
6/13/17	On 6/13/17 Head Counselor 6 reported to PUPD.	Weapon possession	Participant involved in fights with other Participants claimed to have gun. Claim not confirmed by PUPD following safety search.
6/13/17	On 6/13/17 Head Counselor 6 reported to PUPD. On 6/15/17 Dr. Weaver filed internal report and IRB report.	Assault	Participant in fight with another Participant. Participant arrested and dismissed from Study. Other Participant transported to hospital and received medical treatment.
6/14/17	On 6/14/17 Head Counselor 2 reported to PUPD.	Assault	Report that Participant had a knife. No weapon found.
6/15/17	PUPD called. Head Counselor 2 filed internal report on 6/15/17.	Assault	Fight between Participants. No arrests made.
6/15/17	Parent of participant called PUPD. Head Counselor 2 filed an internal report on 6/16/17.	Assault	Participant grabbed another Participant's neck. No arrests made.
6/16/17	Head Counselor 2 filed internal report on 6/16/17.	Injury	Participant injured during basketball game and transported to the hospital for treatment of fractured wrist.
6/17/17	Head Counselor 3 filed internal report on 6/17/17.	Assault	Participant pushed another Participant in response to bullying.

6/19/17	Head Counselor 7 filed internal report on 6/20/17. Witness report to PUPD on 7/27/17.	Bullying, Battery, racial and sexual harassment	Door to male Participant's room was opened while his pants were down. Other Participants taunted him by falsely suggesting that he was engaged in masturbation. In retaliation, the Participant verbally harassed and choked another Participant.
6/20/17	Counselor 5 reported via Slack app on 6/20/17. Head Counselor 2 emailed Dr. Weaver on 6/20/17. Dr. Weaver filed IRB report on 7/7/17 and Title IX report on 7/17/17. Witness report to PUPD on 7/20/17.	Sexual harassment, sexual assault	Multiple reports of sexual harassment and sexual assault of female Participants by male Participant who was dismissed from the Study the following day.
6/20/17	Head Counselor 5 emailed to Dr. Weaver on 6/20/17.	Physical Altercation	Fight between Participants.
6/21/17	Parent called Dr. Martin on 6/21/17. Dr. Martin reported to Dr. Weaver on 6/21/17.	Inappropriate Contact	Female Participant told her mother that a male Participant was "messin" with her.
6/21/17	Head Counselor 4 emailed Dr. Weaver on 6/21/17.	Bullying	Participant verbally harassed other Participants.
6/21/17	Head Counselor 4 filed an internal report on 6/21/17.	Injury	Participant lost toenail when toe caught in door when "goofing around" with other Participants. Participant treated at hospital and released.
6/21/17	Dr. Weaver reported to parent on 6/21/17.	Mental health concern	Participant referred for health care.
6/22/17	Head Counselor 1 emailed Dr. Weaver on 6/22/17. Witness report to PUPD on 7/26/17.	Assault and harassment	Participant threw pebbles at and slapped two other Participants.
6/22/17	Head Counselor 1 orally reported to Dr. Weaver on 6/22/17. Witness report to PUPD on 7/26/17.	Inappropriate physical discipline	Driver slapped Participant on the leg during van trip. Study Staff member restricted from further driving assignments

6/24/17	Counselor 3 orally reported to a head counselor 6/24/17. PUPD called that day. Witness report to PUPD on 7/20/17. PUPD CSA report on 7/20/17.	Aggravated assault	Male Participant intentionally burned another male Participant with a sauna rock while unsupervised in Co-Rec. Participant treated [REDACTED]
6/24/17	Counselor 4 emailed Dr. Weaver on 6/24/17.	Violent and profane outburst	Participant reacted violently and profanely when asked to clean mess.
6/27/17	No report.	Injury	Participant injured hand while punching wall. Participant taken to urgent care facility for medical treatment.
6/27/17	No report.	injury	Participant slipped and fell while playing outside. Taken to urgent care facility for medical treatment of injured ankle.
6/27/17	Counselor 4 emailed Dr. Weaver on 6/28/17. Head Counselor 1 filed Internal report on 6/29/17.	Sexual harassment	Several male Participants at "sleep over" in a room in Tarkington Hall made profane and sexually offensive and threatening comments to a female Counselor. The Counselor resigned from her position due to concerns for her safety and safety of Participants and Study Staff.
6/28/17	PUPD called. Head Counselor 1 filed internal report 6/29/17.	Argument	Argument between two female Participants. No arrests made. One Participant left Study.
6/29/17	Head Counselor 7 emailed Dr. Weaver on 6/29/17.	Assaults, bullying, harassment	Email details multiple problems with male Participant's behavior. Participant dismissed from Study the following day.
6/30/17	Head Counselor 4 filed Internal report on 6/30/17. Dr. Weaver filed IRB report on 7/7/17. Witness report to PUPD on 7-26-17.	Bullying, emotional disturbance	Participant was bullying other Participants and requested to be sent home. [REDACTED] Participant dismissed from the Study that day.
6/30/17	Head Counselor 4 filed Internal report on 6/30/17. Dr. Weaver contacted parents on 6/30/17.	Self-harm.	[REDACTED] Participant received medical treatment and was permitted by her mother to remain in the Study.

6/30/17	Conferences Student Intern called PUPD on 6/30/17. Head Counselor 4 filed internal report on 7/1/17. Dr. Weaver filed IRB report on 7/7/17.	Fight	Fight among Participants. No arrests made. One of the Participants was dismissed from the Study that day for previous incidents of misconduct.
6/30/17	Head Counselor 4 filed internal report on 7/1/17. Dr. Weaver filed IRB report on 7/7/17.	Illness.	Participant complained of ailment. Participant was transported to the hospital and received medical treatment.
6/30/17	Head Counselor 4 filed internal report on 7/1/17. Dr. Weaver filed IRB report on 7/7/17. Witness report to PUPD on 7/26/17.	Bullying, fighting	Fight among Participants. One Participant is dismissed from Study on the following day.
7/4/17	Counselor 2 filed internal report and CSA report on 7/5/17. Witness report to PUPD on 7/26/17.	Sex offense	In the early hours of 7/5/17, a female Participant reported unwanted sexual touching by a male Participant during a van trip. The van was driven by Dr. Weaver.

Beginning of Session 2

7/11/17	Head Counselor 3 filed internal incident report 7/11/17.	Injury	Participant [REDACTED] and was transported to the hospital for medical treatment.
7/12/17	On 8/7/17 PUPD obtained internal email to Dr. Weaver.	Sexual harassment	Male Participant made sexual advance to female lab technician.
7/13/17	Parent emailed Dr. Weaver on 7/13/17.	Sexual activity	Parent reported that daughter was engaged in consensual "sexual activity" with a male Participant while both were unsupervised. Female Participant was removed from the Study by her parents.
7/15/17	Camp manager emailed Dr. Weaver on 7/16/17.	Inappropriate behavior by Counselor	Male Counselor reported to be "favoring" two female Participants. He allowed them to remain with him after scheduled bedtime and instructing others to go to bed. He posted a photo on social media

	Witness report to PUPD on 8/2/17.		depicting the female Participants' heads on his thighs/lap. Counselor not terminated.
7/15/17	Participant report to PUPD on 7/19/17.	Aggravated Assaults	Participant choked one participant and assaulted another participant.
7/17/17	Participant report to PUPD on 7/19/17	Attempted Sexual Assault, Threats, Intimidation, Assault	Female Participant forced herself on top of a male Participant and forced his face toward her crotch while both were clothed. This is the incident that was reported in the media as "attempted rape." The male Participant also reported that on another occasion the female Participant assaulted him and threatened to rape him.
7/17/17	Participant report to PUPD on 7/24/17.	Sexual Assault	Female Participant tried to pull down the pants of a male Participant and attempted to stick her fingers in his anus.
7/18/17	On 7/18/17 Head Counselor 7 filed an internal report and emailed Dr. Weaver and camp manager, who reported incident to PUPD on 7/19/17. Dr. Weaver filed Title IX report on 7/19/17 and IRB report on 7/21/17.	Sexual Exploitation	Female Participant made a nude video of a female Participant in the shower area without her knowledge or consent and posted it on social media. The video was viewed by other Participants who informed her of its existence. The female Participant who made the video had been dismissed from the Study the day before.
7/20/17	Head Counselor 3 emailed camp manager on 7/20/17.	Sexual harassment	Participant made and distributed sexually graphic imagery of a Counselor on social media.
Unknown	Participant report to PUPD on 7/24/17.	Crime threat	Participant allegedly threatened to have father shoot another participant.

PURDUE

UNIVERSITY

DEPARTMENT OF NUTRITION SCIENCE

TO: Camp DASH Staff

FROM: Connie Weaver 765-412-2695
Email: weavercm@purdue.edu

DATE: June 14, 2017

SUBJ: Protocols for Campers' Safety

Camp DASH directors met with a campus safety team including environment, residence hall, police and fire personnel today. This was to develop a plan of action for handling conflicts and other safety concerns.

1. Contact police immediately for behaviors that constitute a crime against a person. This means touching someone in an angry, threatening manner or a sexual aggression. They would like to speak with those involved before it escalates into a felony.
2. Counselors should intervene early in the cases of outburst of anger that involve intimidation. To be clear Camp DASH staff are responsible for camper behavior not the residence hall staff. Residence hall staff are there to facilitate your facility needs.
3. Conferences will provide a procedures and the form for reporting all incidences involving crimes against persons. Reports must be made even when the incidence does not involve the police.
4. When campers are becoming difficult to manage, use de-escalating tactics to redirect their energy. Fountain runs have been very successful towards this end in past camps. The police are concerned that they have too much free time scheduled between 9:00-11:00 p.m. They suggest planned activities and going to bed earlier.
5. The fireman are to be used as paramedics even for something as simple as a scraped knee. Call 911 and they will help us free of charge.
6. Medications should never be unsecured. They will be kept in a locked box in the staff office. When they are put into baggies for imminent distribution and are out of the locked box the room must never be unattended while unlocked.

Communication lines are from counselors to leadership team to camp Directors. Do not hesitate to ask your questions or bring me your concerns.

From: Weaver, Connie M
Sent: Sunday, July 02, 2017 12:55 PM
To: Forman, Michele R <mforman@purdue.edu>
Subject: Camp DASH efforts to improve safety

CAMP DASH efforts to improve safety:

Things that have been done:

1. Seven campers have been dismissed for poor behavior. These individuals were involved in incidents. This eliminates the individuals associated with violence in incidence reports that are believed to be instigators or responsible for making either campers or counselors unsafe.
2. Working with Psychological Services. They agreed to provide therapy to one camper and it is benefiting him greatly. They have also offered to provide services to counselors. We are negotiating an arrangement for a graduate student and faculty mentoring for future summers. I just emailed the Director to see if services could be provided for second session this summer.
3. I have enlisted the help of DeWayne Moffitt from Lafayette Tecumseh Middle School who has a rich background in camps for high risk adolescents among others. He has assessed the camp and helped me to make some of the difficult decisions in dismissing campers. He will come to camp Monday and Tuesday and engage the participants by judging a talent show and other activities. His presence is formidable and yet engaging. He will become more involved second session.
4. I hired a new counselor who comes highly recommended for his involvement with inner city high risk youth in Indianapolis and am in the process of hiring a female counselor from a similar background. The week he has been on board has helped campers and counselors tremendously as he related to some campers with familiarity of their circumstances in areas our college student counselors have no exposure.
5. The first attachment is a template for camp rules that I will be adapting for Camp DASH for second session. Realize the campers have already signed a code of conduct and we have character references for them. The second attachment is a letter prepared by Kyla Houston from Conferences and Chief Cox from the police department to send home with families.
6. I am working with Christelene Horton, Quality Assurance Specialist, Research Regulations for an evaluation in request from the IRB. Christine will be shadowing camp after her vacation.
7. I have implemented incident reporting using a form developed by Kyla Houston from Conferences. I manage resolutions to the incidence reports as they come in though I usually know about the incident prior to receiving the report as I'm available to counselors all the time. I learned Friday that Kyla expected me to share them with her which I started doing immediately after learning this. I thought it was intended for management internal to Camp DASH. I am also preparing a log of these incident reports.
8. The police are doing regular patrols at the request of housing. Last night the patrol officers commented on how most of the kids are good and things seemed good now that I have removed troublemakers. I plan to keep a vigilant watch for additional trouble.
9. Code of Conduct, character references and safety training were developed from 11 sessions of Camp Calcium in coordination with Purdue.
10. For the Code of Conduct, children assent and parents' sign after the information is reviewed with them.
11. Have established minute by minute communications electronically with counselors, staff et al to inform: what is happening; scheduling; and provides 24-7 texting to maintain communications.
12. Every aspect of each incident Dr. Weaver has: engaged with the counselors who were on sight when the event occurred; with the child; with the parents; and the police.
13. Training of counselors was a week long and included: safety; fire; police using items developed in number 9.
14. NIH Program Office has been alerted of the incidents.

15. The DSMB has been alerted. All incidents were logged in and will be submitted to the Purdue IRB and DASH DSMB.
16. Campers will submit response to a survey at the end of the first session to gather input on their impressions, desires for change and the positive aspects of the first session.
17. All medications are stored in a locked secure box in a locked room with access only by the nurse and nursing student to prepare daily prescriptions; counselors are responsible for handing out medications to participants and watching them take the meds.
18. Ratio of counselors to campers is no less than 1:4-5 24-7.

Things that I intend to do for next summers:

1. Require a \$100 deposit to hold a place for a camper. Currently, there is a \$100 activity fee per session but they can opt to have it withheld from their remuneration. It is my judgement that very few of the campers we dismissed due to behavior problems could have afforded this deposit.
2. Revise the screening application to include questions to learn if the prospective camper has been in therapy and for what.
3. I will ask IRB if we can do background checks on campers.
4. Incorporate a staff from Psychological Services.

Things to be done for next session:

1. Have an orientation day on the first day of the second session to: inform campers about camp policy, expectations, changes and post rules visibly throughout the hallways. Using the responses from the campers to the end of session I survey, we will discuss how we value their input, how we have changed the session to meet their wishes, and how we partner with Police, Fire and others to make camp a safe, positive experience.
2. Have the Police in attendance during orientation to foster a positive spirit with the campers.
3. Maximize activities to reduce energy load that adolescents carry with them by fostering more evening and day time physical activities.
4. Highlight behavior appropriate to use of the Co-Rec and other shared facilities.
5. Re-educate counselors about the roles of partners i.e. psychology, DeWayne Moffitt and others so they are apprised.
6. Highlight the cross cultural experience for the campers by introducing counselors from other countries and let the campers ask those from abroad about their way of life.

Sincerely,

Connie M. Weaver, Ph.D.
 Distinguished Professor
 Director, Women's Global Health Institute
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<http://www.cfs.purdue.edu/fn/campcalcium>

<https://ccehub.org/resources/243>

<http://www.purdue.edu/hhs/nutr/campdash/>

<http://www.purdue.edu/womensglobalhealth>

From: Forman, Michele R
Sent: Monday, July 03, 2017 5:05 PM
To: Klingerman, Trenten D; Akridge, Jay T; Garimella, Suresh V; Zelaznik, Howard N; Elliott, Stephen John; Ladisch, Christine M; McCuskey, Beth M
Cc: Forman, Michele R; Weaver, Connie M
Subject: RE: RE: Camp DASH efforts to improve safety
Flag Status: Flagged

Folks

Dr. Weaver and I are delineating the ramifications of a study shut down in the near future.

In this email, we explore the financial and scientific ramifications of shutting down Camp DASH for the second session of the first year:

1. There are several grants pending or awarded for this research study beyond Dr. Weaver's own U01 including a recently funded NSF grant, ILSI contract, A2milk grant. All sponsors and PIs will be facing the challenges of agencies who support them and their institutions being placed under a magnifying glass regarding their competency and the support of their institutions for this study. Anyone who needs to go back to study section with preliminary data from Camp DASH is jeopardized because the expectation will be that a full summer of data will be provided; further with the advent of the shut-down, study section will not trust that there will be assurances for the continuation of the study. Thus all of us who are resubmitting will pause if not decline to resubmit if the study is stopped.
2. As regards compensation for the adolescent and their families, the expectation based on the consent form is for each to be provided \$750 at the end of the summer. One half of the amount will be provided tomorrow at the end of the first session. The parents expect their child to participate in the second summer session and there is no verbiage regarding the termination of the study in the consent. The parents will need to address the following for the second summer session:
 - a. Where the child will spend his/her time during the day
 - b. How the parent will have to pay for their child care and room and board that they were expecting.
3. The parents will be expecting full compensation with the shutting down of the Camp. Therefore Purdue needs to have a financial plan in place to pay for all these incurred obligations and answer the families and all others involved about the reasons for the shut down as well as provide assurances that in the future the Camp will occur.
4. Other financial obligations relate to: expected summer employment of staff, counselors, and faculty plus finances to reschedule flights for those who came from all over the world to train on Camp DASH. The numbers of individuals are as high as 125. We are investigating whether the contracts can be terminated for many of these individuals.
5. Other financial obligations include: contracts to Tarkington, the Co-Rec, Conferences, transportation, food that has been prebought.
6. There is a significant matter related the Purdue name because of so many partnerships with industry on this project and research partners like Johns Hopkins University, UCSD, Penn State, Florida International, IU School of Medicine and Cincinnati Children's Hospital, Blofortis, U of Iowa, Esoterix. The embarrassment and potential anger by research partners is considerable and has implications for future collaborations.
7. Further there is a domino effect that loss of this study would downsize the portfolio for the CTSI base and substantially reduce the amount of money that comes into this state on the CTSI grant which is up for renewal as we write.

8. Importantly the study design depends on the cross-over to the second session. Without the cross over, we need 5 times the number of subjects to equal the number of subjects lost and could not be corrected in the current grant.
9. Word from NIH is very distressing. Purdue cannot count on retaining the grant if they choose to throw away this initial investment.
10. Camp DASH is on the radar scientifically to address one of the most pressing problems of the future generations of the U.S. The military wants to have fit recruits, the life expectancy of adolescents is shorter than ours and the healthcare costs of chronic disease are escalating. Camp DASH is an intervention that could lead the way in changing dietary guideline for adolescents, and improving quality of life as well as longevity should the dietary intervention be successful.

We would appreciate your response to our concerns.
Thanks

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From: Weaver, Connie M
Sent: Sunday, July 02, 2017 12:55 PM
To: Forman, Michele R <mforman@purdue.edu>
Subject: Camp DASH efforts to Improve safety

Things that have been done:

1. Seven campers have been dismissed for poor behavior. These individuals were involved in incidents. This eliminates the individuals associated with violence in incidence reports that are believed to be instigators or responsible for making either campers or counselors unsafe.
2. Working with Psychological Services. They agreed to provide therapy to one camper and it is benefiting him greatly. They have also offered to provide services to counselors. We are negotiating an arrangement for a graduate student and faculty mentoring for future summers. I just emailed the Director to see if services could be provided for second session this summer.
3. I have enlisted the help of DeWayne Moffitt from Lafayette Tecumseh Middle School who has a rich background in camps for high risk adolescents among others. He has assessed the camp and helped me to make some of the difficult decisions in dismissing campers. He will come to camp Monday and Tuesday and engage the participants by judging a talent show and other activities. His presence is formidable and yet engaging. He will become more involved second session.
4. I hired a new counselor who comes highly recommended for his involvement with inner city high risk youth in Indianapolis and am in the process of hiring a female counselor from a similar background. The week he has been on board has helped campers and counselors tremendously as he related to some campers with familiarity of their circumstances in areas our college student counselors have no exposure.
5. The first attachment is a template for camp rules that I will be adapting for Camp DASH for second session. Realize the campers have already signed a code of conduct and we have character references for them. The second attachment is a letter prepared by Kyla Houston from Conferences and Chief Cox from the police department to send home with families.
6. I am working with Christelene Horton, Quality Assurance Specialist, Research Regulations for an evaluation in request from the IRB. Christine will be shadowing camp after her vacation.
7. I have implemented incident reporting using a form developed by Kyla Houston from Conferences. I manage resolutions to the incidence reports as they come in though I usually know about the incident prior to receiving the report as I'm available to counselors all the time. I learned Friday that Kyla expected me to share them with her which I started doing immediately after learning this. I thought it was intended for management internal to Camp DASH. I am also preparing a log of these incident reports.
8. The police are doing regular patrols at the request of housing. Last night the patrol officers commented on how most of the kids are good and things seemed good now that I have removed troublemakers. I plan to keep a vigilant watch for additional trouble.
9. Code of Conduct, character references and safety training were developed from 11 sessions of Camp Calcium in coordination with Purdue.
10. For the Code of Conduct, children assent and parents' sign after the information is reviewed with them.
11. Have established minute by minute communications electronically with counselors, staff et al to inform; what is happening; scheduling; and provides 24-7 texting to maintain communications.
12. Every aspect of each incident Dr. Weaver has; engaged with the counselors who were on sight when the event occurred; with the child; with the parents; and the police.
13. Training of counselors was a week long and included: safety; fire; police using items developed in number 9.
14. NIH Program Office has been alerted of the incidents.
15. The DSMB has been alerted. All incidents were logged in and will be submitted to the Purdue IRB and DASH DSMB.
16. Campers will submit response to a survey at the end of the first session to gather input on their impressions; desires for change and the positive aspects of the first session.
17. All medications are stored in a locked secure box in a locked room with access only by the nurse and nursing student to prepare daily prescriptions; counselors are responsible for handing out medications to participants and watching them take the meds.
18. Ratio of counselors to campers is no less than 1:4-5/24-7.

Things that I intend to do for next summers:

1. Require a \$100 deposit to hold a place for a camper. Currently, there is a \$100 activity fee per session but they can opt to have it withheld from their remuneration. It is my judgement that very few of the campers we dismissed due to behavior problems could have afforded this deposit.
2. Revise the screening application to include questions to learn if the prospective camper has been in therapy and for what.
3. I will ask IRB if we can do background checks on campers.
4. Incorporate a staff from Psychological Services.

Things to be done for next session:

1. Have an orientation day on the first day of the second session to: inform campers about camp policy, expectations, changes and post rules visibly throughout the hallways. Using the responses from the campers to the end of session I survey, we will discuss how we value their input, how we have changed the session to meet their wishes, and how we partner with Police, Fire and others to make camp a safe, positive experience.
2. Have the Police in attendance during orientation to foster a positive spirit with the campers.
3. Maximize activities to reduce energy load that adolescents carry with them by fostering more evening and day time physical activities.
4. Highlight behavior appropriate to use of the Co-Rec and other shared facilities.
5. Re-educate counselors about the roles of partners i.e. psychology, DeWayne Moffitt and others so they are apprised.
6. Highlight the cross cultural experience for the campers by introducing counselors from other countries and let the campers ask those from abroad about their way of life.

Sincerely,

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