POSITIONAL DIFFERENCES IN HELMET IMPACT EXPOSURE RATES IN HAWAIIAN HIGH SCHOOL FOOTBALL ATHLETES

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List of Abbreviations

Centers for Disease Control ……..……..... CDC

Impacts per Exposure …… Imp/E

Head Impact Exposure …….. HIE

Head Impact Telemetry System ……..……..…… HITS

Sports Related Concussion ……..……..…… SRC

Traumatic Brain Injury ……..……..…… TBI

Repeated Head Impact ……..…....…… RHI

Chronic Traumatic Encephalopathy ……..……..…….. CTE

Head Injury Criteria ……..…… HIC

Balance Error Scoring System ……..……..……..... BESS

Immediate Post Concussion Assessment and Cognitive Testing …….. ImPACT

Standard Assessment of Concussion ……..…… SAC

Sensory Organization Test …….. SOT

Animated Neuropsychological Assessment Metrics ..…….…… ANAM

California Verbal Learning Test ……. CVLT

Sideline Response System …… SRS

Interquartile Range ……..…….…… IQR

Gadd Severity Index …….. GSI

Concussion Assessment, Research, and Education ……..…….. CARE

Risk Weighted Exposure ……..…….. RWE

Department of Education …..…….. DOE

Part One

Abstract

Context*:** Previous research has shown the importance of analyzing head impact exposure (HIE) among high school football players, yet few studies explore the difference across position groups. Therefore, the purpose of this study was to analyze head impact frequency between position groups.Objective:*** Quantify the difference of impacts per exposure (Imp/E) between position groups in high school football during the 2019 and 2021 seasons. ***Design:*** Cross-sectional study. ***Setting:*** Three high school varsity football teams on O'ahu. ***Patients and Participants:*** 200 varsity football players featuring 69 offensive/defensive linemen (16.0 ± 0.9 yrs, 180.4 ± 7.7 cm, 87.0 ± 22.4 kg; linemen), 51 linebackers/running backs/tight ends (16 ± 0.8 yrs, 176.6 ± 7.1 cm, 83.7 ± 13.8 kg; backers) and 80 wide receivers/defensive backs (16.1 ± 1.0 yrs, 175.4 ± 6.3 cm, 71.72 ± 10.32 kg; skills). ***Main Outcome Measures:*** Games, practice, and total Imp/E analyzed across positions, teams, and years. ***Results:*** A difference was observed across position groups ($P<0.001$). Season was not found to be a factor ($P<0.446$). A significant interaction ($P<0.002$) exists between team B and C ($P=0.021$), but not between A and C. Post-hoc analysis confirms that the backers (3.37 [95% CI: 2.80, 3.949]) experience a higher HIE compared to linemen (1.55 [95%CI: 1.067, 2.049]) and skill players (1.57 [95%CI: 1.124, 2.035]). ***Conclusion:*** To our knowledge, this is the first study of this size comparing position groups in terms of Imp/E of the given population across two seasons. These data demonstrate that linebackers and running backs experience more impacts per exposure, indicating the influence of running the ball or directly defending the ball has on increased head impacts. Future research, such as player risk-compensation, impact location across position groups in the given population, or alteration of coaching techniques and style of play could contribute to overall risk reduction of head impact exposure.

Key Words: Head impact frequency, Riddell Insite, traumatic brain injury
Word Count: 349

Key Points:

Running backs, tight ends, and linebackers experienced a greater number of impacts per exposure in high school football players.

Analyzing head impacts per exposure has the potential to identify factors contributing to increased frequency of head impacts and patterns across position groups within a team.

Introduction

Head impact exposure (HIE) in sport activity is a multifactorial term that may includes the frequency of head impacts (e.g., number of head impacts per practice), magnitude of the impacts (e.g., peak linear acceleration), the location, and cumulative history of head impacts for an individual athlete.[2] Various strategies and technologies exist to analyze sport participation and HIE, including telemetry devices, tackling interventions, or limiting live contact during practice sessions. By monitoring head impacts, researchers, health care professionals, and coaches can analyze HIE to develop strategies to mitigate the number of head impacts that athletes sustain during practice sessions, scrimmages, or games.

Head impact telemetry systems (HITs) are commonly accelerometers embedded into helmets to determine the linear and angular accelerations of head impacts in collision sports that allow for analysis of HIE to occur.[4] Different systems exist that incorporate accelerometers, including mastoid patches, mouth guards, or sensors that lie beneath air bladders or internal padding in helmets. Data collected by these devices provide insight in regards to head impact biomechanics using measures including angular acceleration and velocity, magnitude, and impact location. HIT devices play a vital role in monitoring the biomechanical factors related to head impact exposure, proving to be a tool in the research of head impacts among athletic populations. The health risks associated with repetitive head impacts (RHI) should be explored at various ages to determine the possibility of long-term cognitive effects. Conducting analyses on HIE at different levels of athletic competition and specific position groups aid in understanding the importance of impact biomechanics such as impact frequency or location.

Monitoring of head impacts in football has been studied at all levels of competition. Research on the youth, college, and professional sports levels, monitor head impacts specifically in football to describe the characteristics and biomechanical properties involved with head impacts.[5,6,7,8] Previous studies observed HIE and head impact biomechanics in high school football players noted position groups to depict general differences seen in biomechanical properties of HIE, such as vertical and rotational acceleration, overall frequency and HIT severity-profile (HITsp).[10,11] However, the independent positions or denoted groups were not involved in a further analysis for the purpose of head impact frequency comparison.[10,11] To our knowledge, no study has focused specifically on comparing head impacts by position group, team, or season in high school football population. Analyzing specific positional groups may allow for potential behavior modification and overall risk reduction in the sport. Therefore, the purpose of this study was to compare helmet impact frequency between position groups across two high school varsity football seasons.

Methods

Study Design

This study implemented a cross-sectional design. Three teams and four seasons of data were included in this analysis and are shown as Team A (2019), Team B (2019, 2021), and Team C (2021). The initial season of data collection included 99 participants, 46 from Team A and 53 from Team B, recruited from two private high school football teams in Hawaii. The second season of data collection will consist of a total of 101 participants, 53 players from Team B, and 46 players on Team C. Players and parents signed approved assent and/or consent forms prior to study initiation (Human Studies Program #2019-00370; Appendix).

Participants

Attendance for each session (games, practices, or scrimmages), was recorded to standardize impact frequency (helmet impacts per session) and allow for identification and elimination of spurious impacts occurring outside of monitored session windows, such as impacts occurring in locker rooms or dropped helmets. Participants with fewer than 20 head impacts were excluded from the analysis (n=5 subjects). Participants that appeared to have malfunctioning software or equipment were not considered for analysis (n=2). Impact data were organized according to the participant's primary positions and divided into position categories: linemen (offensive and defensive linemen), backers (tight ends, running backs, and linebackers), and skill players (cornerbacks, safeties, and wide receivers). Height and weight were drawn from official rosters and age was calculated from the date of August 1st for each season of analysis. See Table 1.

Instrumentation

Athletes wore a properly fitted Riddell Speedflex helmet, embedded with a Riddell (Rosemont, IL) InSite head impact system sensor. The InSite system consists of an overliner sensor that lies atop the helmet air bladders. Sensors connect via bluetooth to a handheld monitor that communicates real-time head impact data triggered by impacts greater than the 99th percentile. This technology collects impact frequency, intensity, and magnitude of head impacts with the corresponding impact location. An on-site field research assistant collected relevant data for each session (practice, game, or scrimmage), such as start and stop times during sessions when helmets are worn to mitigate spurious impacts. Data points were then exported and filtered using excel.

Data Interpretation

Head impact data were retrieved from the Riddell Insite System and sent to the HuTT808 (Helmetless Tackling Training) research team. Exports were then cross referenced with participant exposure start/stop times and overall team attendance. Athletes that wore sensor helmets and participated in a team session are considered an exposure. Athletes that wore helmets but did not participate in a session (athlete return to sport protocols or acclimatization periods) were excluded for a given day. Total number of impacts were divided by total number of exposures for standardization. Exclusion criteria was applied and data were imported to SPSS (28.0.1.1) for subsequent analyses.

Statistical Analyses

The three independent variables considered were year, teams, and position groups. The dependent variable was impacts per exposure (Imp/E) across three types of sessions (total, games, or practices). Normality was assessed utilizing a Shapiro Wilks test and equality of variance via Levene's test. A three-way ANOVA at an alpha level of $\alpha = 0.05$ with follow-up Tukey's post hoc HSD-test and was performed to identify any differences across the independent variables. All statistical analyses were completed using IBM SPSS Statistics software; Version 28.0.1.1.

Results

Participant demographics are shown in Table 1.

Table 1. Demographic Means and Standard Deviations

	Age (yrs)			Height (cm)			Weight (kg)		
Linemen	16.1	±	0.9	182.4	±	7.3	106.2	±	22.6
Backers	16.0	±	0.9	176.4	±	6.8	83.6	±	13.5
Skills	16.1	±	1.0	174.6	±	6.8	70.5	±	10.4
Total	16.1	±	0.9	177.8	±	7.8	86.4	±	22.7

Data drawn from official rosters and DOB (as of 8/1 of given season)

Normality Assessments

Levene's test for homogeneity of variance and Shapiro Wilks analyses were completed to detect and evaluate the variances and distribution of the data. The variances of each of the dependent variables (total impacts per exposure, game impacts per exposure and practice impacts per exposure) were significant ($p<0.001$) based on Levene's test. Histograms depict the distribution of Imp/E for each variable shown in Figure 1 (A,B, and C respectively). Results of the Shapiro Wilks analysis confirm that each dependent variable of total, game, and practice impacts per exposure are not normally distributed (<0.001). This result is consistent across both seasons.

Figure 1A. Frequency of Total Impacts Per Exposure

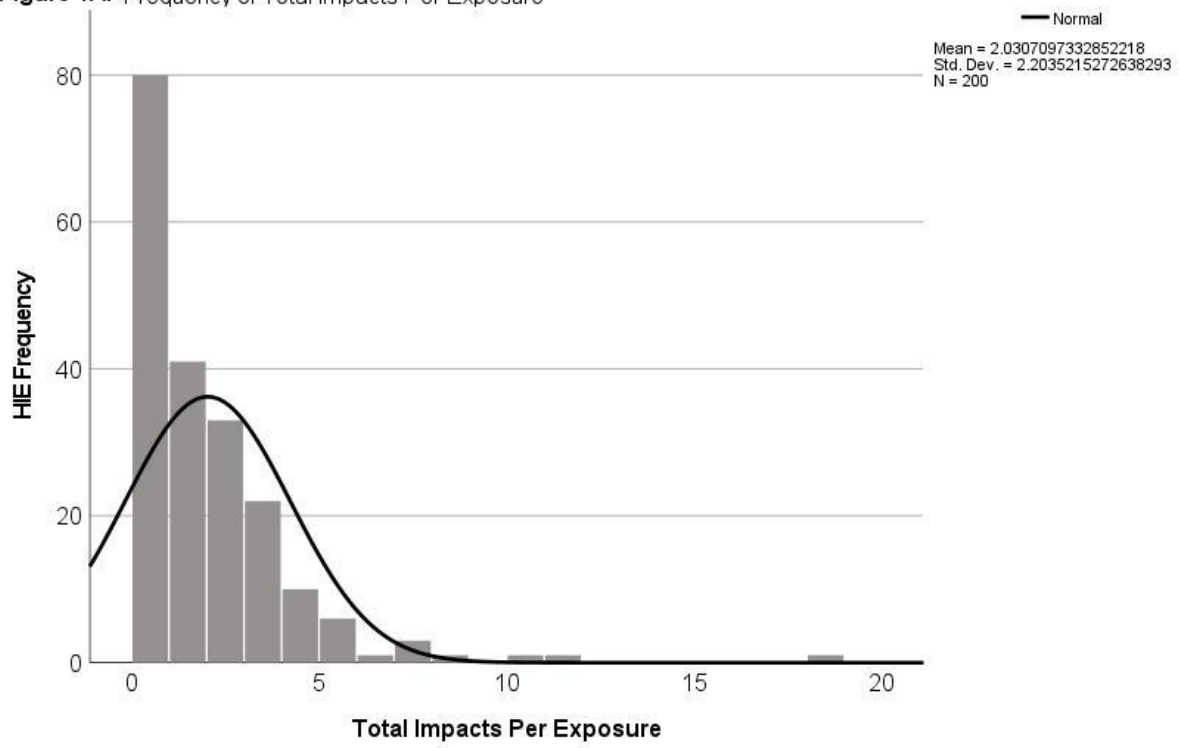


Figure 1B. Frequency of Game Impacts Per Exposure

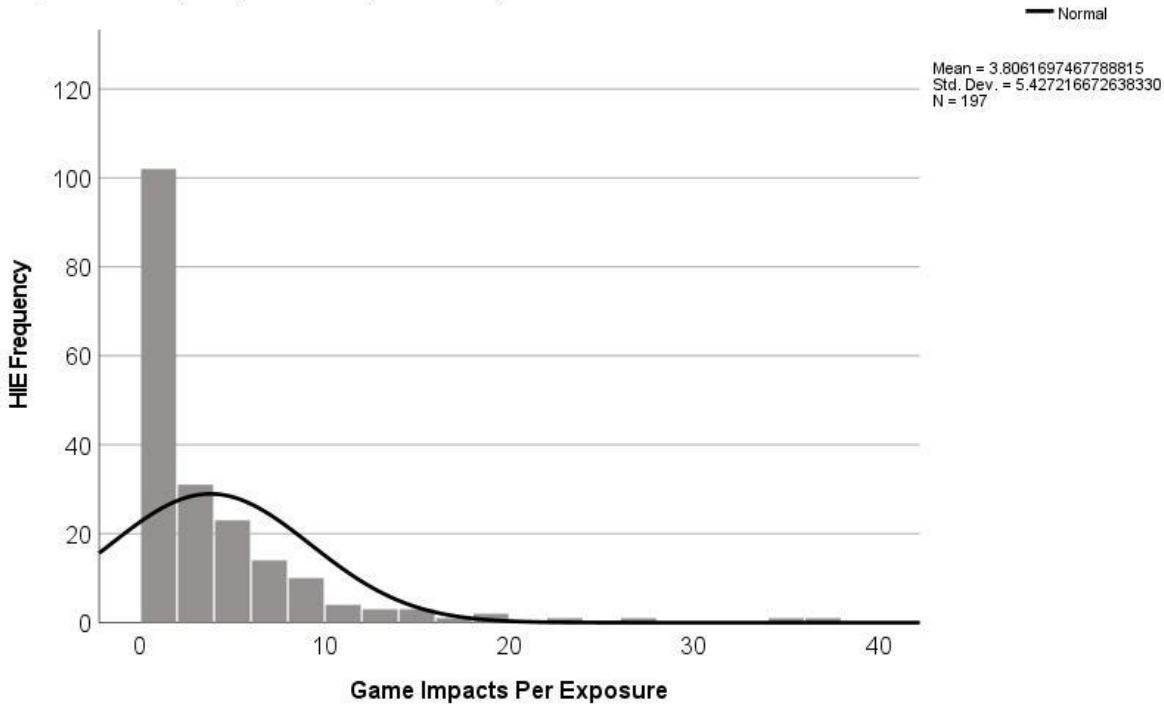
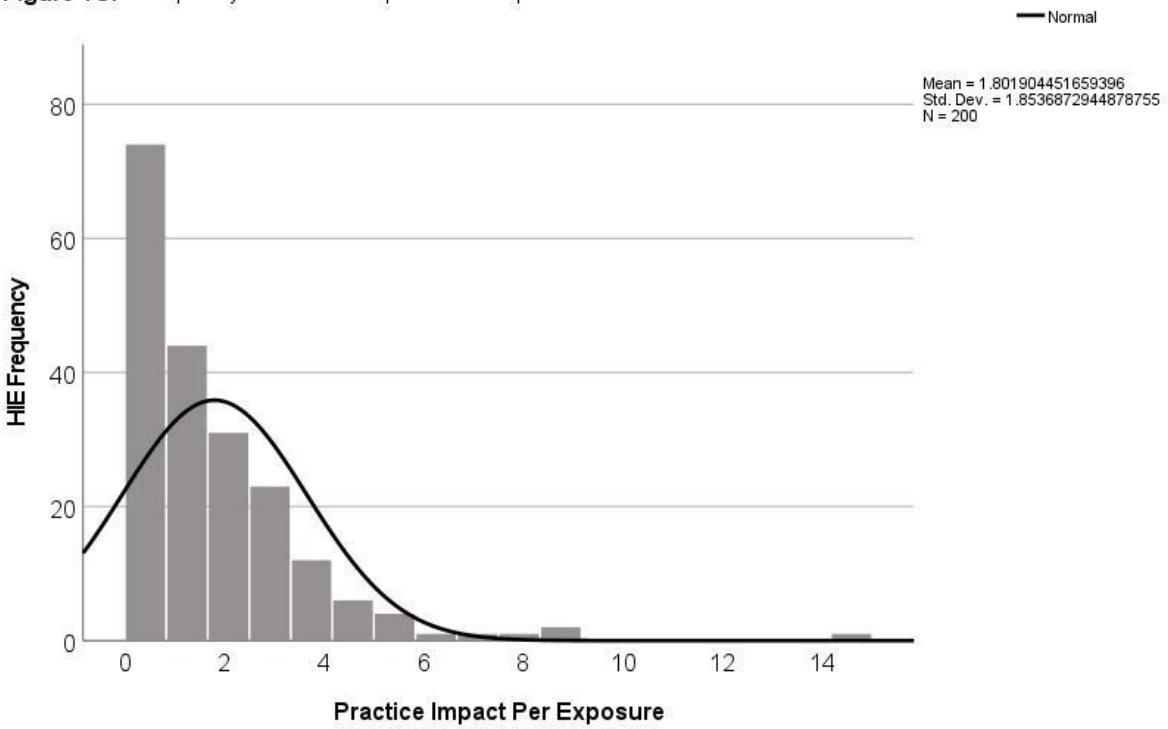


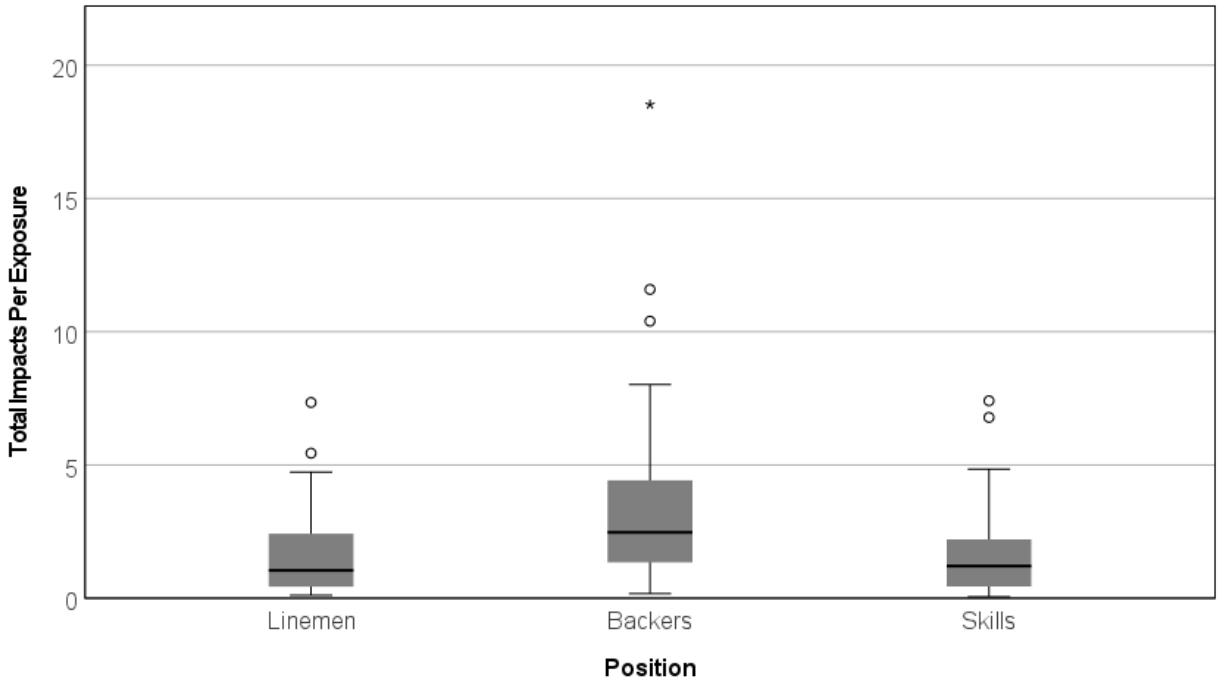
Figure 1C. Frequency of Practice Impacts Per Exposure



ANOVA and Tukey's Post-Hoc

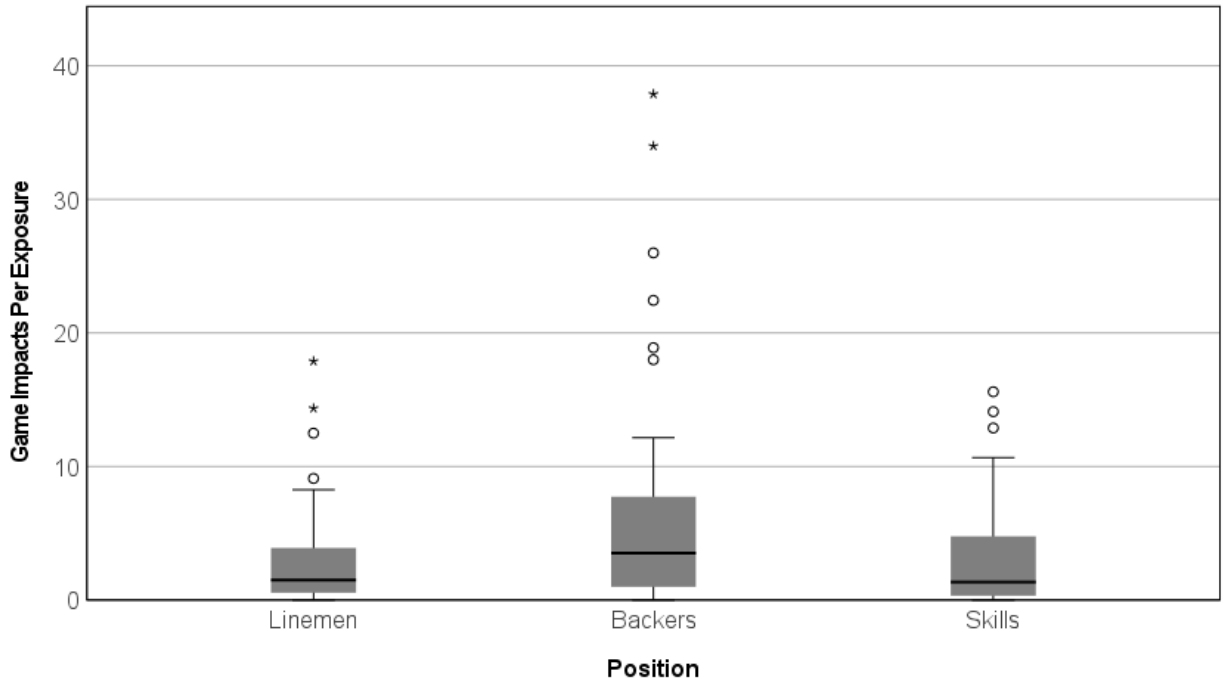
Analysis of total game and practice HIE was found to be statistically significant by position ($P<0.001$). Outliers, with high numbers of impacts per exposure in each position are shown using ⋆ & ○ symbols, respectively. See Figure 2A.

Figure 2A. Total Impacts Per Exposure by Position



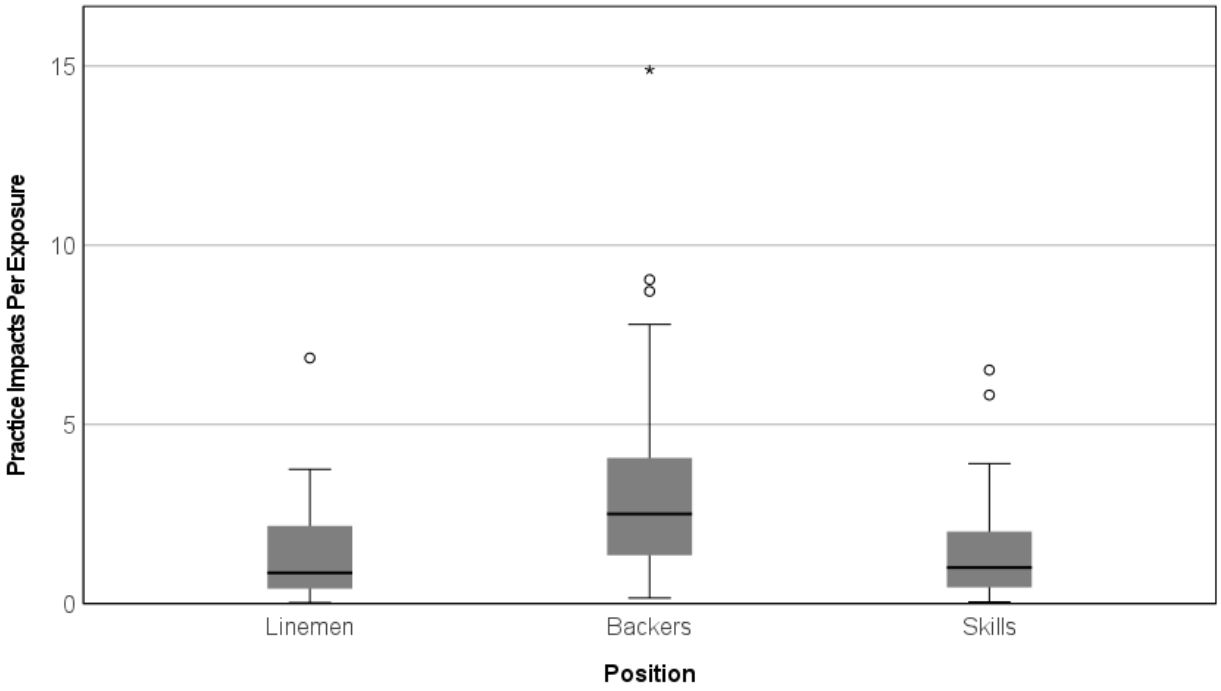
Outliers, with high numbers of impacts per exposure in each position are shown using ⋆ & ○ symbols, respectively. The post-hoc analysis confirmed that the backers (3.37 ± 3.27) had greater HIE compared to the linemen (1.55 ± 1.41) (P<0.001) or skill players (1.57 ± 1.46) (P<0.001). Linemen and skills were not different from each other in terms of total Imp/E (P=0.998). Game total impacts per exposure was statistically significant (P<0.001) by position with backers (6.45 ± 8.38) being statically different from linemen (2.76 ± 3.49) (P<0.001) and skills players (3.03 ± 3.64)(P=0.01) confirmed with post-hoc tests. See Figure 2B.

Figure 2B. Game Impacts Per Exposure by Position



A similar pattern exists for practice impacts per exposure. The backers group (3.00 ± 2.67) was different from linemen (1.39 ± 1.24) and skills (1.38 ± 1.24) (P<0.001). The post-hoc confirms that no difference existed between skills and linemen (0.998), but the backers differ statistically (P<0.001). See Figure 2C.

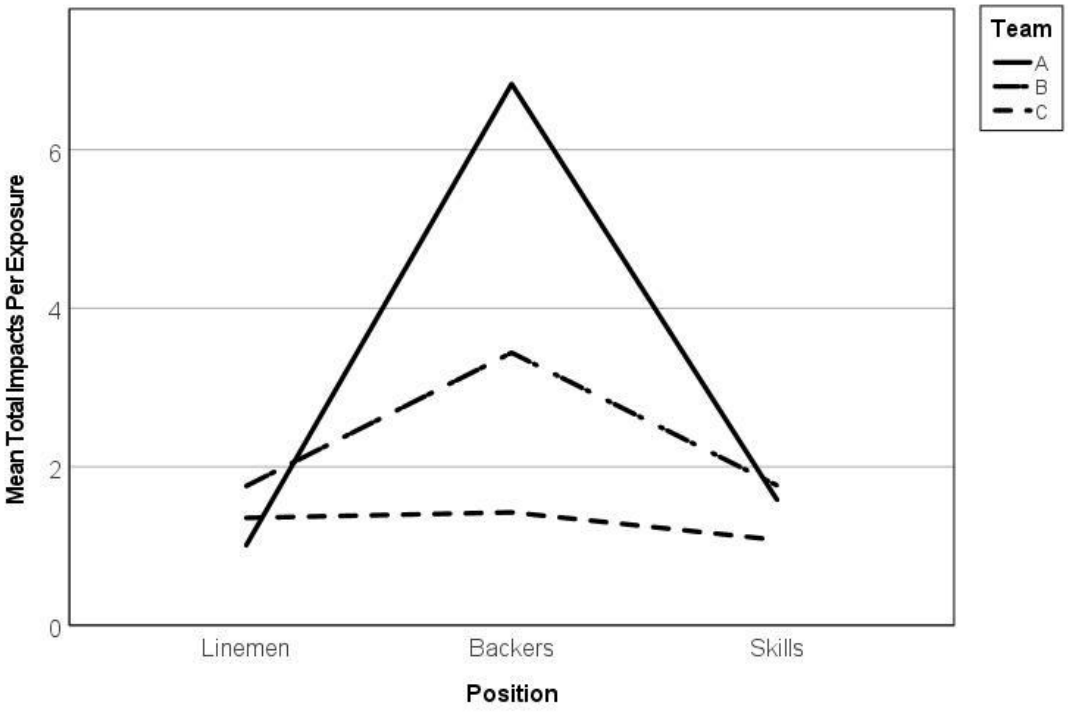
Figure 2C. Practice Impacts Per Exposure by Position



An interaction effect (P=0.002) exists between position and team for total impacts per exposure. Each team exhibits different patterns by position. The backers group on Team A displayed the highest frequency of head Imp/E, compared to Team B and C. For all 3 teams, no difference exists between linemen and skills, see Figure 3A. There is no significant difference in total, games, or practice impacts per exposure by

position and year (P=0.446).

Figure 3A. Interaction of Total Impacts Per Exposure by Position and Team



A similar pattern was found for game and practice impacts per exposure. See Figures 3B and 3C. A significant interaction exists between position and team (P=0.003). There was no significant interaction between position and year for all teams

Figure 3B. Interaction of Game Impacts Per Exposure by Position and Team

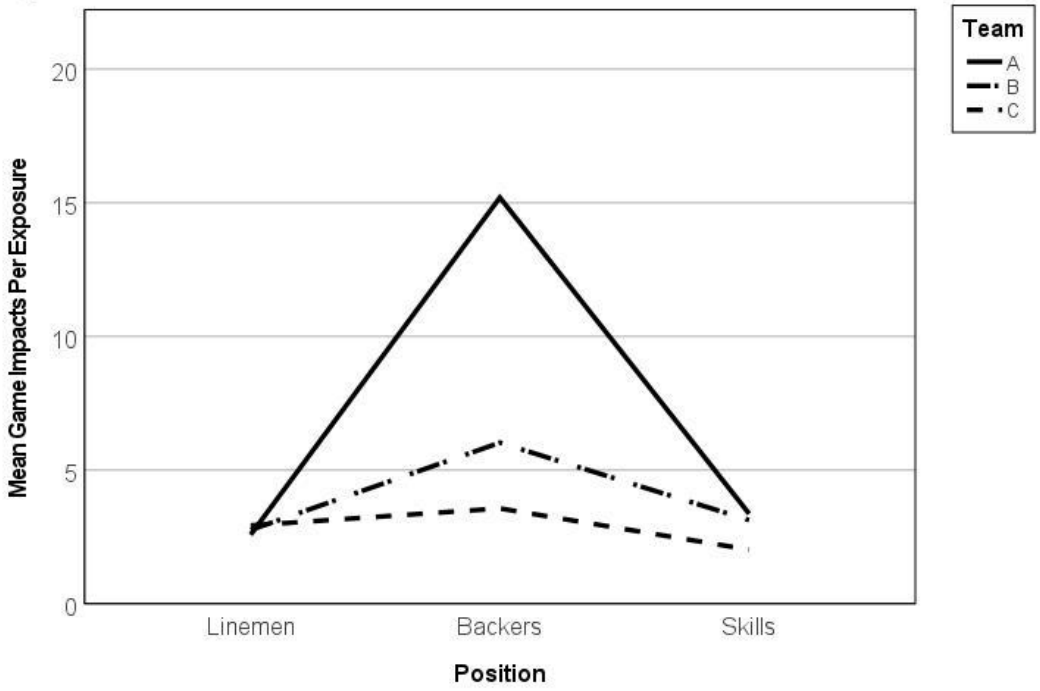
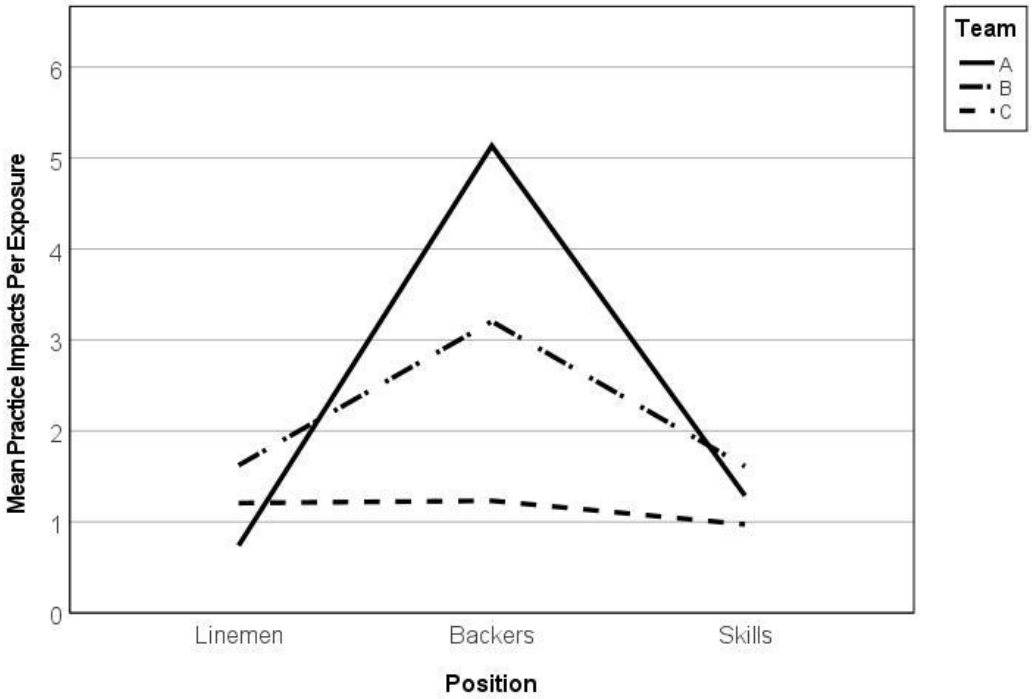


Figure 3C. Interaction of Practice Impacts Per Exposure by Position and Team



(P=0.162). Total practice impacts are significant by position and team (P=0.016). No significant interaction exists between position and year (P=0.579).

Discussion

The most important finding of our study was that the linebackers, running backs, and tight ends experienced a greater number of impacts per exposure. This is in contrast to previous research, which found that linemen experience a greater number of total head impacts when compared to other position groups at the high school level across games and practices.[10,11] The primary difference from our findings may be due to the fact that ours were scaled by exposures. To our knowledge, only one other study at the high school level assessed head impacts by exposures.[8] Broglio et al., standardized HIE similarly to the present study and however the main outcome measures were not to compare by position, but rather HIE changes after limiting full contact practices.[10,11] Our findings add to those existing literature by including impacts scaled by exposures and comparison of participants separated by position groups.

Results indicated that differences exist across position groups in terms of total, game, and practice impacts per exposure for all teams combined. It is unknown which factors affected the greater number of frequencies for the backers position group. It is possible that coaching technique, years of experience, athlete size, position group coaching style, and personal techniques have the ability to alter/affect the increased number of head impacts.

More research and background information should be studied and collected prior to participation regarding factors of tackling philosophy and helmet impact biomechanics in similar studies. Looking forward, collecting baseline measures of varsity football teams to increase subject study size can give researchers a better idea of positional differences in Imp/E in the given population. Analysis of junior varsity or athletes with less experience in competitive football would be beneficial for comparison. Future studies of the same data set should analyze impact location and its relation to position groups to get a better idea of the overall differences found in varsity high school football players.

Limitations

Certain limitations exist due to the structure of the analysis. It would be difficult to track athletes who play both offense and defense during a given session, as one research individual located at each school, considering the different plays, units and changes that may occur during a practice, game or scrimmage. It's also important to note changes due to possible injury or lack of player eligibility for academic reasons. It also may be possible for some impacts to occur and be counted for a skills player that might be playing linebacker or running back, nonetheless, the head impacts are

counted for a skill athlete. There were unequal distributions found in normality and lack of equality in variance, but this is to be expected for a larger sample size. Additionally, the sample was homogenous in the fact that they were all high football players in a single state, so removal of outliers would not be logical. Steps were taken to ensure the authenticity of the data as outlined previously. Data collections occurred in the 2019 and 2021 seasons. Due to COVID-19 interruptions, the 2021 season featured a mandatory pause on public schools sports and activities issued by the Department of Education (DOE), affecting Team C. Team B continued to practice resulting with a greater total number of exposures due to the extended season. Team A only participated in one season of data analysis due staff changes.

Conclusions

Monitoring head impact exposure in high school football players provided data on positional differences across teams and seasons. These findings highlight the large differences in head impacts found in both individual positions and teams. Clinicians can use this knowledge to advise behavior modification and instruction across position groups; allowing us to guide future interventions aimed at reducing the number of head impacts an athlete sustains and overall total risk reduction.

Financial Disclosures

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Part Two

Literature Review

Introduction

According to the Centers for Disease Control and Prevention (CDC), a concussion is defined as a type of brain injury caused by a bump or jolt to the head or body that causes the brain to move rapidly inside its cavity.[1] This has the potential to alter the brain's chemicals and damage its cells. Repetitive head impacts or head impacts of greater magnitudes and intensities have the ability to alter cognitive state, commonly referred to as a concussion. Various strategies and technologies exist, including telemetry devices, tackling interventions, or limiting live contact during practice sessions, to monitor head impacts or possibly alter susceptibility to extraneous head impacts within the sport.

Head impact exposure (HIE) in sport activity is a multifactorial term that may include the frequency of head impacts (e.g., number of head impacts per practice), magnitude of the impacts (e.g., peak linear acceleration), the location, and cumulative history of head impacts for an individual athlete.[2] Researchers, health care professionals such as athletic trainers, and coaches analyze HIE to develop strategies to mitigate the number of head impacts that athletes sustain during practice sessions, scrimmages, or games. Head impact telemetry systems (HITs) are commonly accelerometers embedded into helmets to determine the linear and angular accelerations of head impacts in collision sports that allow for analysis of HIE to occur.[4] Different systems exist that incorporate accelerometers, including mastoid patches, mouth guards, or sensors that lie beneath air bladders or internal padding in helmets. Data collected by these devices provide insight in regards to head impact biomechanics

using measures including angular acceleration and velocity, magnitude, and impact location. HITS play a vital role in monitoring the biomechanical factors related to head impact exposure, proving to be a tool in the overall research of head impacts among the athletic population. The health risks associated with repeated head impacts (RHI) should be explored at various ages to determine the possibility of long-term cognitive effects. Conducting analyses on HIE at different levels of athletic competition and specific position groups aid in understanding the importance of impact biomechanics such as impact frequency and location.

Monitoring of head impacts in football has been studied at all levels of competition to one degree or another. Research on the youth, college, and professional sports levels monitored head impacts specifically in football to describe the characteristics and biomechanical properties involved in HIE, as well as to explore the impact of rule changes or proper tackling. Previous studies observed HIE and head impact biomechanics in high school football players while dividing and noting their position groups. However, the independent positions or denoted groups were not involved in a further analysis for the purpose of head impact frequency comparison.[6,7] No study has focused specifically on comparing these head impacts by position group in high school football population, nor have any divided them into three groups; backers, linemen, and skills. To this end, the purpose of this study is to compare helmet impact frequency between three player position groups during two Hawaiian high school varsity football seasons.

Head Impact Exposure and Health Risks

Over 4 million concussions occur each year,[9] concussions are acute injuries, but suggested to have the possibility of contributing to long term negative health consequences, with Monitoring HIE is a beneficial way to analyze, and develop possible ways to mitigate the number of head impacts an individual sustains while playing sports. A HITS is able to provide biomechanical variables that may be used for analysis of head impacts in a given population.

McAllister et al[10] published a literature review to determine the long term cognitive and neuropsychiatric effects that head impacts and repetitive concussions have immediately and later in life such as chronic traumatic encephalopathy (CTE), recurrent migraines and other pathologies. Although, it's possible to sustain a high frequency of head impacts without sustaining concussions, commonly referred to as subconcussive *impacts,* it is important to denote the risk of sport participation and implications it might have on the functioning of an individual later in life. Two studies published by Crisco and Broglio analyzed head impact biomechanical variables including linear acceleration, rotational acceleration, jerk, force, impulse, and impact duration in collegiate and high school football players, respectively.[1,7] However, their work did not focus on the long term effects of repetitive head impacts in these populations. Many studies review graded symptom checklists or return to play programs that feature balance and performance-based measures for those sustaining concussions, but few focus on the effect of the subconcussive blows in varying sports.

Broglio et al. previously examined HIE in 95 high schoolers across 4 seasons, while collecting cognitive and symptom data during the preseason, post season and

following concussive events.[11] Athletes wore a HITS device to monitor head impact frequencies and magnitudes. As expected, symptoms increased and cognitive function decreased following a concussion. There was no correlation between any of the head impact exposure variables and any of the cognitive function or performance tests. This denotes the principle that utilizing a head impact telemetry device is not feasible in terms of diagnosing a concussion or to predict the actual severity of a TBI but rather its use for possible injury threshold.

Gysland et al. studied the potential relationship between subconcussive impacts and its effect on neurological function in collegiate football players.[12] Forty-six athletes were assessed across five neurological tests including the Balance Error Scoring System (BESS), Standard Assessment of Concussion (SAC), Sensory Organization Test (SOT), Animated Neuropsychological Assessment Metrics (ANAM), and the graded symptom checklist and were collected at preseason and postseason timepoints. A HIT device collected biomechanical variables including frequency and magnitude of head impacts. It was observed that collegiate football players may sustain 1177.3 ± 772.9 head impacts over the course of the season. Despite the relatively high number of head impacts compared to other literature[11] there was not a significant effect on pre and postseason concussion measures and short-term neurologic impairment. This enforces the idea that more research is required to denote the influence of subconcussive head impacts and their relation to long term conditions and health risks such as CTE.

McAllister et al[13] reviewed the influence of subconcussive impacts, observed in a different athletic population. 214 football and ice hockey athletes participated in this study across 3 NCAA Division I institutions. In addition, 45 noncontact athletes were

included in this study from nordic skiing, track and crew. All athletes wore helmets during each exposure from Riddell or Easton. ImPact testing was completed and compared pre and postseason as well as the California Verbal Learning Test (CVLT). An average of 469 impacts was observed across all athletes. Athletes participating in contact sports performed more poorly on the CVLT compared to the noncontact participants (24% vs 3.6%; $p < 0.006$) after the conclusion of the season. Overall, it is possible that repetitive head impacts may affect the learning in some collegiate athletes. However, findings are consistent with other studies[11] in the principle that these subconcussive impacts do not directly influence short-term cognitive performance. This study also enforces the idea that contact sports place a greater risk for brain injury on athletes but the long term effects need to be further explored.

Beckwith et al[14] published a study that compares the frequency and severity of head impacts on days with concussions versus days without observed concussions in football players. 1,208 athletes from 8 colleges and 6 high schools were fit with HITS to wear during team sessions over a six year period. 161,732 total impacts were collected. 95 concussions were sustained and defined by any altered mental state reported by the team's medical staff. Eight athletes sustained 2 concussions and one athlete experienced 3 concussions ultimately totaling 105 concussive events. Collegiate athletes sustained 68 concussions, and high school athletes experienced 37 concussions. Overall, the days with higher frequency and increased magnitudes of head impacts were the days associated with concussion diagnosis. These findings imply that modification of higher contact days in high school and collegiate football may reduce the

likelihood of concussions. Mitigation strategies should be implemented in terms of contact vs non-contact drills and the overall practice structure to reduce RHI exposure.

Head Impact Telemetry Devices

Monitoring of HIE has been analyzed utilizing different kinds of HITS, including accelerometers placed on/within mastoid patches, mouthguards, and specialized helmet sensors of different shapes and styles. Consistent output of these devices is required in order to denote effectiveness of measuring impact location, frequency, and linear acceleration accurately within the given product to promote their use.

A clinical review conducted in 2016 by Williams et al[5], found that only 10 of 24 accelerometers measuring head impacts have evidence supporting their use in American football and ice hockey. Linear acceleration, rotational acceleration and impact location were collected and analyzed. Clinical implications of their use should not be as a diagnostic tool, but for their use in conjunction with other tools for analysis of head impacts. Indirectly, head impact telemetry systems are able to reduce the risk of exposure to injury through rule and/or coaching changes.

In 2017, a systematic review by O'Connor et al[15], found that the HITS (Riddell) system was the most commonly used telemetry system for monitoring HIE. Out of 61 peer-reviewed articles, 53 of them analyzed this device. Subjects consisted of athletes across five different sports in individuals aged 6-24. Despite the widespread use of the given device, specificity rates were low and the error rates remained high. Therefore, the clinical utilization of varying head impact systems should be for sideline monitoring of impacts as opposed to diagnosing concussions in athletes.

Few studies have analyzed the accuracy of head impact telemetry systems utilizing video verification. However, a study conducted by Campbell et al[16] , aimed to

compare its accuracy utilizing footage of a highschool football team and their special teams unit to the monitoring system. 22 athletes and 218 different plays were included in the study over a single football season. Each athlete wore a Riddell Revolution, Speed or Speedflex helmet for use with the HIT system encoder, consisting of 6 accelerometers. Two different video analysis approaches were used, and it was denoted that the HIT system had a 69% sensitivity, 72% specificity and 70% accuracy when compared to videos of the given plays. It is concluded that utilization of these systems should be taken with a grain of salt. Many limitations exist surrounding this study. Only one camera view was taken, which may explain the excessive impact events that were not seen by the video reviewers. Overall, head impacts observed vs head impacts triggering an impact on different telemetry systems requires further research to denote its reliability and accuracy as an instrument.

Jadishcke et al[4] published a study in 2013 examining the accuracy of a HITS in football helmets using a skull cap embedded into helmets to detect pressure and a Hybrid III dummy compared to volunteers. The Hybrid III dummy is widely used as the gold standard to measure linear and angular acceleration. By fitting helmets on volunteers (63, 14-20 year old football players) and a dummy, it is possible to compare fit preference regarding helmet pressure, which is an important part of utilizing HITS. It was found that utilizing a dummy does not accurately predict impacts, due the difference of fit regarding pressure in the helmet. Majority of volunteers complained of discomfort in the frontal region of the head amongst impact locations. Overall, the range of impact severity of HITS is so wide that in terms of denoting concussions, it is

inaccurate. This strengthens the suggestion of utilizing HITS for monitoring of head impacts rather than detecting possible traumatic brain injuries.

Helmet Impact Exposure Across Levels of Competition

Youth HIE

Collecting HIE in different populations is important due to the ever changing level of competition, skills, years of experience, and age. Utilizing HIT devices allows for data collection regarding impact locations, frequency, and magnitude. By monitoring these impacts researchers can aim to alter behavior of coaches and athletes in hopes of indirectly decreasing the likelihood of TBI football at all levels of competition including youth, high school, collegiate and professional. Implementing the use of accelerometers on younger athletes can allow for earlier intervention to provide safer tackling techniques.

Dorman et al[17] explored HIE in youth football players, ages 11-14 for eight consecutive seasons. 103 athletes participated in this study which consisted of a community-based tackling program with coaches that remained consistent over the 8 seasons of data collection. A total of 33,519 head impacts were collected utilizing the Head Impact Telemetry (HIT) System and Sideline Response System (SRS) by Riddell (Elyria, OH). The numbers of practices and games changed year to year ranging from 22-41 practice sessions and 9-11 games. Overall, the predominant location for head impacts observed across the 8 seasons was the front of the helmet. This observation is consistent with studies that monitored head impact location among high school football players.[7,18] It was found that that number of impacts decreased as the study

progressed. In 2019, the athletes experienced ⅛ of the number of impacts compared to 2012. This suggests that the use of a HITS that is monitoring head impacts indirectly allows for a decrease in the number of head impacts sustained among football players/program participants.

Savino et al[18] compared HIE in youth football players to high school aged football athletes using Riddell InSite Impact Response System, developed from the HITS/SRS device. 98 individuals (45 youth and 53 high school athletes) participated in this observational cohort study for two seasons. Data collected included pre/post demographic information provided by parents/medical professionals. The InSite system was used at each practice and competition using a sensor embedded into the helmet, spanning 5 different locations. It was concluded that across the two seasons, impacts among the youth football players increased significantly. Those that participated in the study from one season to the next did not have a significant difference in the number of sustained impacts. This may be explained by limiting full contact practices, the less likelihood of athletes playing both offensive and defensive positions or fewer active plays.

A study to observe HIE in youth football players aged 6-9 was conducted by Daniel et al.[19] On a team of 26 athletes, 7 players received Riddell Revolution helmets with a six degree of freedom head acceleration measurement device (6DOF) due to their high attendance and participation. This 6DOF device consists of 12 total accelerometers that connect to a computer on the sideline. Impact location for each head impact was recorded and overall accelerations were divided by session type. A total of 748 impacts were observed, 441 impacts were recorded during practice

sessions. Each player averaged about 107 head impacts, none experiencing a concussion or TBI. The most common location for head impacts was the sides of the helmet, approximately 36%. This study denotes the difference of HIE in youth football players as well as discussed the increased number of head impacts in practices. Further research is needed on the population and a greater number of subjects would be beneficial to analyze HIE of this age group.

A study conducted by Munce et al[20] in 2015 featured 22 athletes, ages 11-13 for an entire season. The goal of the study was to characterize the association of HIE and neurologic function. Athletes participated in neurological screening including a symptoms checklist, balance measures, oculomotor performance, and reaction time, pre and post season. Participants wore helmets containing HIT sensors that collected impact location, duration, frequency and magnitude. The helmets were worn for 9 games and 27 total practices. A total of 6,183 head impacts were observed, 61% occurring during practice (3,787). Conclusively, there were no statistically significant neurological impairments following the season. Overall, these findings were consistent with the hypothesis that youth football players will experience a less HIE than high school and collegiate athletes. However, the numbers in terms of magnitude of head impacts is similar to those of high school and collegiate athletes.

High School HIE

Broglio et al[7] completed a study of head impact biomechanics amongst high school football players. 35 varsity athletes were fitted with Riddell Revolution helmets embedded with a HITS device that connects to a sideline computer. Data collection included an entire football season of practices including preseason, and games; 13 games, 55 practice sessions. A total of 19,224 head impacts were sustained and included in the analyses. It was denoted that the defensive line athletes sustained the greatest number of impacts per session when compared to offensive players and defensive skills athletes. Rotational acceleration was collected, finding that game impacts (mean= 1669.79 ± 1249.41 rad/s2) generated more rotational acceleration than practice impacts (mean =1468.58 ± 1055.00 rad/s2) likely due to level of competition. It was shown that offensive and defensive line players were similar in this category using post-hoc analyses. Linear acceleration showed similar numbers between defensive linemen and offensive skill players ($P < .01$). Defensive linemen ultimately had greater linear accelerations than defensive skills athletes and offensive linemen ($P< .01$). It was observed that impacts to the front of the head were predominant among this population across all players and positions, yielding the greatest linear acceleration. Player concussion rates were not a collected variable in this specific study. Given varying limitations such as limited subject numbers, HITS should continue to be researched in the field before use as a diagnostic tool, despite the beneficial biomechanical information they collect.

In a separate study, Broglio[26] et al monitored HIE and its implications on regulation of full contact practices among high school athletes. It's assumed that by limiting full contact practices in football can mitigate the risk of subconcussive impacts that may lead to increased risk of head injury with long-term effects. This cross-sectional study collected data on head impact magnitude and frequency across a 15-week season. 42 varsity athletes sustained a total of 32,510 impacts that were compared by player position and types of session. Following statistical analyses, linemen sustained the greatest number and highest magnitude of impacts, followed by tight ends, linebackers, running backs, and skill players. Impacts were then broken down by type of session (practice, non contact practice, and game). Notably, contact practices (n=36) had 16,346 impacts and non contact practices (n=21) only had 1998 impacts. Games (n=14) had 14,166 impacts across the entirety of the season. Findings suggest that limiting full contact practices to once per week could result in an 18% decrease in the number of impacts sustained across the season, while completely eliminating full contact practices could result in a 39% decrease in head impacts.

A study conducted by Kercher et al[22] analyzed head impact frequency and how they vary by type of drill. USA football classifies drills into categories based on the type of contact: *air, bags, control, thud, and live*. It is to be expected that the head impact frequency will increase as the level of intensity increases in terms of contact. Over the course of the 2019 season, 24 high school football players participated in 46 practices, 1 scrimmage, 9 JV games, and 10 varsity games. Utilizing a sensor embedded into their mouthguards (Vector), 6016 impacts were gathered. Conclusively, *live* drills collected a higher number of impacts (113.7±17.8 hits/player) and greater magnitudes

(2,657.6±432.0 g) when compared to *air* drills, (7.7±1.9 hits/player) and (176.9±42.5 g) respectively. Unlike previous studies, no position difference was found across the 24 athletes likely due to the limited number of subjects. Notably, the highest level of impacts took place during *live* and *thud* drills coinciding with USA football's guidelines on drills. In terms of clinical implications, this study denotes the idea that limiting higher levels of contact drills in high school football practices may minimize head impact burden. This concept correlates with previous studies regarding monitoring head impact frequency of young athletes.

In 2013, Urban et al[23] conducted research with two purposes; to quantify HIE in high school football players and to develop an impact analysis method. A total of 40 athletes were given helmets embedded with HITS to wear over the course of an entire season. 16,502 head impacts were noted and biomechanical analysis was completed on a team and individual level. Median impact data for each player spanned from 15.2 to 27.0 g with an average value of 21.7 (±2.4) g. In addition, an impact exposure metric using concussion injury risk curves was created in order to cumulatively quantify exposure for each athlete. Impacts were weighted by risk due to rotational and linear acceleration in addition to the combined probability of injury associated with both. Risks were summed at the conclusion of the season. As expected, impact frequency was greater during games (15.5 g) compared to practices (9.4 g), similar to previous studies. Although the impacts/game averages were higher, the median exposure was greater during practices, suggesting that athletes are exposed to a greater number of high level impacts during practice. Over 60% of the athletes had greater than 50% total risk exposure for practice impacts. This study suggests that analyzing head impact

exposure across high school aged athletes will provide insight into the overall safety of the sport and improve the overall understanding of head impacts and head injuries.

It is evident that monitoring HIE amongst high school football players should continue to be explored as it provides insight on head impact biomechanics. A more in depth comparison of head impact frequency by position may be beneficial. Monitoring the HIE of collegiate athletes has also been researched and provides an interesting comparison among the populations especially in terms of reported concussions and positional comparisons.

Collegiate HIE

Schnebel et al[24] published a study comparing the impact force and injury patterns of high school football players to NCAA Division I athletes with the goal of improving protective headgear. 40 athletes at the University of Oklahoma and 16 athletes at a high school were recruited for participation during the 2005 season. Each player wore a HITS device embedded into their helmets for practices and games. Positions groups were denoted as skills and linemen for analysis. At the collegiate level, 54,154 impacts were observed, and 8,326 at the high school. As expected the collegiate players experienced a greater magnitude of impacts (>98g) compared to the high school players. Consistent with other studies (Crisco et al, 2011), linemen experienced a greater frequency of head impacts and skills players sustained greater magnitude of impacts. Conclusively, differences between collegiate and high school football players exist. There are significant limitations to this study concerning the difference in subject numbers at each level respectively.

A study conducted in 2007 by Guskiewicz et al[25] featured 88 NCAA Division I football players across 3 seasons (3 fall, 2 spring) at UNC. Players were fit with helmets embedded with head impact telemetry systems. Pre and post season demographic and medical data was collected in addition to head impact. Posturals stability testing (Sensory Organization Test (SOT)) , neuropsychological testing (Automated Neuropsychological Assessment Metrics (ANAM)) and symptom grading checklists were completed prior to the season starting. Over the course of five seasons, 104,714 impacts (102.8 g magnitude average) were collected across 88 subjects. Of these players, 11 sustained concussions and one participant sustained 2 concussive

events. Given the data collection regarding symptoms and different forms of neuro/physical testing, there was no relationship or correlation with linear/rotational acceleration. This suggests that concussive events occur at wide ranges of magnitudes and other factors may play a role in whether a concussive event will occur. However, a greater sample size with a higher occurrence of concussions would be required. This study might have some error given the possibility of athletes not reporting concussive events and/or symptoms. It was also noted that half of the sustained concussions occurred from contact to the top of the head, which corresponds with current research among football players. Overall, this study further demonstrates the idea of HITS devices as a tool to monitor greater magnitudes of impacts, but should not be expected to detect concussions.

HITS biomechanics in the NCAA at a Division I institution was investigated by Asken et al[26] in 2018. 47 athletes were included in this study out of the University of Florida. Over the course of two seasons, 169 practices were included for analysis. Unlike previous studies, game impacts were not observed or included as the focus was to analyze 'friendly fire' impacts amongst teammates. Impacts were categorized into two position groups: lineman (offensive and defensive), and non-lineman (backers and skills). Information regarding drill types (14) and athlete dress (full pads, shells, helmets only) was collected to explore differences of magnitudes associated with varying practice types. A total of 32,083 impacts were observed, 73.5% of these 'friendly fire' occurred amongst the linemen group. This study observed the difference among drill types in collegiate football, denoting 3 specifically that are considered high risk (>95th percentile) for impacts. In addition, this implies that there are varying

impact frequencies among drills in the college setting, some that may decrease the number of impacts by limiting the amount of time spent on certain drills. This enforces the principle of utilizing a HITS device to monitor practices and possibly mitigate head impacts, even at a D1 institution.

In 2005, Duma et al[27] utilized a HITS that provided sideline staff with real time data regarding HIE. 38 subjects on Virginia Tech's varsity football team wore an in-helmet accelerometer. Throughout the course of the 10 game season and 35 practice days, a total of 3,312 head impacts occurred. The primary focus of this study was to analyze peak head acceleration in combination with recorded concussion. One event was observed with a 267 on the Gadd Severity Index and a 200 on the head injury criteria scale with a peak acceleration of 81 g. The average GSI and HIC recorded were 32 g ± 25 g, 36 g ± 91 g, and 26 g ± 64 g. Conclusively, the HITS proved to be effective at collecting HIE and showed value to provide head impact data that can be used alongside clinical evaluations.

Crisco et al[28] published a study analyzing the frequency and location of head impacts in a NCAA Division I setting. Over the course of a season, 3 teams and 188 athletes participated in this observational study, focusing on individual athletes HIE. Each athlete wore a HITS and impacts were categorized by player session (impact observed in a team session) and team sessions (games, scrimmages and practices) to assure participation on a given day. Head impact frequency and location was analyzed for each subject. Throughout the course of a season, it was observed that collegiate football players may exhibit as many as 1400 impacts to the head (6.3 per practice, 14.3 per game). The number of head impacts per game totaled 3 times the amount of

head impacts per practice. Impact location varied by positions, with linemen and linebackers experiencing the greatest frequency of impacts per game and practice. The only position that did not experience the greatest number of impacts to the front of the head was quarterbacks (back). In addition, impact frequency and location varied significantly between the three teams (Team A being the highest in all categories), which may be explained by differences in coaching philosophy, players themselves, or other factors. This study supports the use of HITS devices as a way of supporting clinical decision making and presenting the idea that data collection can be beneficial to helmet manufacturers.

A separate study conducted in 2011 by Crisco et al[1] analyzed HIE in collegiate football players over the course of three seasons. The overall focus being to quantify head impact magnitude, frequency and location for individual players and compare differences by position. 314 players experienced 286,636 impacts at three different institutions. Notably, the position groups varied in terms of magnitude and frequency. Quarterbacks and running backs experienced the highest magnitude of impacts, while offensive/defensive linemen and linebackers experienced a greater frequency of head impacts ($P<.05$). In addition, offensive linemen experienced the greatest number of impacts to the front of the head which is consistent with previous research. Player position played the largest role on HIE compared to previous literature.[29] Overall, this study quantified the relationship of helmet biomechanics and player position, however many limitations exist. Impacts were only denoted by primary positions, not accounting for those who play both sides of the ball, or differences among coaching techniques.

Regardless, these findings provide insight into the realm of helmet biomechanics and subconcussive blows which may be beneficials to varying professionals in the field.

A CARE consortium study conducted by McCrea et al[29] analyzed the correlation of concussions and HIE in collegiate football players. This observational study included 658 players from six different Division I institutions throughout the 2015-2019 seasons. Athletes wore HITS devices, prioritizing starters over reserve players. A total of 528,684 head impacts were observed. 68 individuals sustained a concussion, 33 occurring during the preseason (48.5%), and 49 (72%) occurred during practice sessions. Interestingly enough, preseason HIE was the greatest each season, even though these practices accounted for just 20.8% of overall sessions. HIE was significantly higher in the month of August (median, 146.0 impacts; IQR, 63.0-247.8) and lowest in November (median, 80.0 impacts;IQR, 35.0-148.0). Overall, this data provides insight regarding the most common time of concussion occurrence. It also allows for teaching opportunities among coaches regarding preseason practices, and the concept of mitigation strategies regarding HIE. In addition, the possibility of altering policy and educating various stakeholders about concussions can aid in decreasing the incidence of concussions at all levels of competition.

In 2019, Stemper et al[3] completed a study as a subset of the CARE consortium.The purpose of this work is to analyze the role of RHI in the onset of concussion in DI football players. The HIE of concussed athletes was compared to the injured individuals controls, matched by player position and team. The volume of HIE was compared to those that did not experience a concussive event for a direct comparison over the same time period. Six Division I varsity programs participated

across three different seasons, totaling 511 subjects. Each athlete wore Riddell speedflex helmets used with a SRS. 424,059 head impacts were recorded with HIE of 34,267 across athletes. 50 athletes experienced recorded concussions, 48 were included for analyses. This was then analyzed by position groups and compared to athlete controls (national averages). 34/48 had evidence of intense HIE on the day of injury. Four of the remaining 14 athletes showed risk weighted exposure (RWE) greater than the 75th percentile of the concussed population. 10 concussed athletes had no evidence of greater HIE on the date of sustained concussion. Conclusively, this study showed that 72% of athletes had severe HIE on the day of their concussion. Overall RHI and the use of HITS provide insight on SRC, but require further evaluations for their validation.

NFL HIE

Little research regarding HIE has been observed at the professional level. Few studies in the NFL focus on HIE between positions and/or concussion occurrence despite the beneficial information that these biomechanical values provide.

Karton et al[30] published a study looking at RHI across 72 NFL players.Video verification was used to quantify impacts in correlation with helmet sensors across eight different player positions from 2009-2015. During 32 regular season games a total of 3,439 head impacts were observed (2,941 confirmed, 498 suspected), not including practice sessions. Among total confirmed head impacts, offensive/defensive linemen experienced the greatest frequency of head impacts, followed by tight ends, running backs and linebackers. Notably, occurring at the front of the helmet which is consistent with previous studies at different levels of competitions. In terms of RHI, quarterbacks experienced the lowest mean 48.9 vs OL mean rank=202.30 and DL mean rank=213.38. Certain implications can be drawn from this given study, including the idea that an NFL player may experience upwards of 1000 impacts during their career, possibly 6000 depending on their time in the league alone. No statistically significant differences were found on magnitude collected by head impact sensors. The effect that RHI has on any athlete involved in contact and collision sports is noted as brain matter is proven to be altered.

An article published by Lessley et al[31] completed a descriptive epidemiology study looking at video verification of head impacts and diagnosed concussions spanning across two seasons in the NFL. Although this study did not utilize a HITS to monitor HIE, it featured a positional comparison. Cornerbacks sustained the most

diagnosed concussions, followed by wide receivers, linebackers, and offensive linemen. 50% of concussions occurred on passing plays, 28% on rushing plays, and 21% on special teams plays. This provides insight as to what specific position groups are sustaining head impacts that correlate to concussive events, but variability in video verification should be noted. More studies should be completed amongst professional football players to further explore HIE. The use of HIT devices may be beneficial to track HIE in this given population.

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Appendix

Protocol Title: Reducing Head Impact Exposure in Hawaiian Football Players and Enhancing Community Awareness and Environment for Head-Safety

Protocol Type: Unified IRB Form

Date Submitted: 01/13/2023

Approval Period: 02/15/2023-02/14/2024

Important Note: **This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.**

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* * * Continuing review * * *

To renew your protocol:

1. Complete this one-page form;
2. If necessary, update any sections of the protocol that need to be updated (e.g., change in contact information, researcher location) and attach any new supporting documents (e.g., researcher training certifications, other IRB approval letters); Note: significant modifications to the protocol must be addressed using the modification application form.
3. Electronically "sign" the application by clicking in the check box on the "Obligations" page;
4. Remember to click "Submit Form" so that the IRB administrators receive your application.

You must answer each question. Input N/A to answer any questions that are not applicable.

NOTE: Documents that contain much of the information required to answer the participant number questions below can be found in the "Event History" section of each protocol.

1. Summary: Number of Participants Associated with the Protocol:

a. Total number of participants approved to date:

375 Participants

b. Number of participants studied since the last approval date:

105 Participants

c. Total number of participants studied since the beginning of the project:

470 participants

d. Number of participants remaining to recruit/enroll (total number of participants approved LESS the total number of participants studied to date):

275 participants remaining to be recruited

e. Please explain if there is a discrepancy in participant numbers (e.g., more participants responded to a survey than had been approved):

No discrepancy to report

2. Summary: Issues associated with the protocol

a. Reasons and number of withdrawals from the research (both subject and investigator initiated) since the last approval date.

71 total participants withdrew from the research. 55 participants to graduation, 7 participants quit the football team, and 9 participants sustained season ending injuries.

b. Number of subjects lost to follow-up since the beginning of the study.

230 subject lost to follow up since the beginning of the study

c. Description and number of any protocol deviations/violations or unanticipated problems (UPs)/adverse events (AEs), particularly those that may have affected the risks to subjects since the last approval date.

Protocol Title: Reducing Head Impact Exposure in Hawaiian Football Players and Enhancing Community Awareness and Environment for Head-Safety

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No deviation/violation, or problems to report

d. Complaints about the research during the last year.

No complaints to report

3. A summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.

No new recent findings, literature, or relevant information to report since last approval date.

4. Description of the remainder of project:

Y Are research participants still being enrolled in the study?

Y Have all enrolled research participants completed study participation?

N Is the research active only for long-term follow-up of enrolled participants?

Y Do you plan to recruit more subjects?

If "No," have all subjects completed all research-related interventions? Note: Protocols must be renewed to continue recruiting participants and/or collect data from already recruited participants.

Y Are you in the data analysis stage?

Y Is the data de-identified?
(If you answered yes to these two questions you can stop and submit a Final Report. If you answered no to one of them please continue).

5. Has approval for this study expired? N

a. Why did approval lapse?

b. What will you do differently in the future to prevent this from happening again?

c. Were any additional research participants enrolled or data collected after the expiration date?

If Yes, describe all activities that continued including number of participants involved and any adverse event or incidents that occurred after expiration of approval.

NOTE: If renewal of the study does not occur before the expiration date of study approval ALL enrollment of participants and DATA COLLECTION must stop at the expiration date. Procedures and treatment needed for the safety of participants should continue but data collected during this time period CANNOT be used for research purposes.

6. Informed Consent:

a. Does this study use a consent form? Y

7. Has there been additional or new information about this study which may affect a subject's willingness to continue their participation, or that may need to be given to prior participants? (Such as safety information, complaints about the research, revised procedures, duration of study, recent literature, etc.) N

If YES, please explain and describe how information was provided or is being provided to current or prior participants.

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8. **If this is a multi-center trial, has the most recent data safety and monitoring report or other summary report been submitted to the IRB since the last review?** Y

   If No, submit a current report (Attach on attachment page).

9. **Summarize all changes in the protocol since it was last approved (e.g., have you modified your protocol during the past year?). Are you planning to request any changes for the upcoming year?**

   A modification may be submitted to increase subject number and to include additional schools into the study.

   NOTE: Do not use this renewal form to propose changes to your protocol. Changes to the protocol should be submitted separately, using the modification form. Submitting protocol modifications using the renewal form may result in rejection of the renewal application.

   List of Protocol Sections (and questions) that have been changed/modified.

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* * * Personnel Information * * *

Starred items indicate required fields whenever that section is completed.

Is this a student led research?* N

Principal Investigator

UH defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator.

Name of Principal Investigator*		Degree (MD/PhD/BSN/etc.)		Title
Murata, Nathan		PhD		Prof, Dean
Email*		**Phone**		**Fax**
nmurata@hawaii.edu		956-7703		956-3106
Research Department		**UH Status Check ALL that apply***		**Mailing Address**
University of Hawaii at Manoa, Kinesiology and Rehabilitation Science, College of Education Dean's Office	X	Faculty		
		Staff		
		Other		

ALL research personnel are required to complete Human Subject Research training.	
Which human subjects research training was completed for this protocol?*	CITI
See memo regarding appropriate human subjects training.	
The Research Compliance Office will verify the last date of completion below.	
Attach file of NIH training certificate in Attachments Section.	

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NIH Completion Date	

Training Details

CourseID	Course	UserID	CourseCompletionDate	CourseExpirationDate
6924024	CITI Health Information Privacy and Security (HIPS) for Students and Instructors	nmurata	10/26/11	
47764093	Exempt Researchers and Key Personnel	nmurata	04/06/22	04/05/25
46957500	Exempt Researchers and Key Personnel - Biomedical Data and Specimens Only IPS	nmurata	03/01/22	02/28/25
18040506	Exempt Researchers and Key Personnel - Biomedical Data and Specimens Only IPS	nmurata	01/29/19	01/28/22
47764092	Exempt Researchers and Key Personnel IPS	nmurata	03/01/22	02/28/25
31442682	Non-Exempt Biomedical Researchers and Key Personnel IPS	nmurata	04/28/19	04/27/22
46957501	Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel	nmurata	03/03/22	03/02/25
28446961	Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel	nmurata	01/29/19	01/28/22
18040507	Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel	nmurata	12/01/15	11/30/18
46957502	Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel IPS	nmurata	03/01/22	02/28/25

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28446962	Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel IPS	nmurata	01/28/19	01/27/22
18040505	Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel IPS	nmurata	12/01/15	11/30/18
6924023	Social & Behavioral Research - Basic/Refresher	nmurata	02/05/13	02/05/16
18040504	Social and Behavioral Responsible Conduct of Research	nmurata	01/29/19	01/28/23

Other Investigator(s)

Name of Other Investigator	Degree (MD/PhD/BSN/etc.)	Title	Research Department	Type of Investigator
Tsuchida, Allison				Co-Investigator
Furutani, Troy				Co-Investigator
Oshiro, Ross				Co-Investigator

Administrative Contact

Name of Administrative Contact, Project Director, or Lab Coordinator	Degree (MD/PhD/BSN/etc.)	Title
Email*	**Phone**	**Fax**
tfurutan@hawaii.edu		
Research Department	**Mailing Address**	

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* * * Subject Checklist * * *

Subject Checklist

Select All That Apply :

X Children and/or students under 18 years of age (including neonates)

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Pregnant women/ fetuses
Prisoners
Military personnel
Adult Volunteers
Economically/educationally disadvantaged
Individuals with impaired decision-making capacity
University students
University employees
Illiterate
Homeless
Public officials/candidates for public office
Institutionalized patients/residents
Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
Healthy Individuals
Other (please specify):

---

* * * Study Location * * *

Study Location

Select All That Apply - NOTE: Check "Other" and input text: 1.) If your study location is not listed, or 2.) If you would like to list details of your already-checked location (e.g., specific school within a school district)

X University of Hawaii, Manoa
University of Hawaii, Hilo
University of Hawaii, West Oahu
University of Hawaii Community Colleges

X School/School District
Hawaii Public School
Hawaii Charter School
X Private school — Pac5 and St. Louis School

Medical Health Care Facility
Queens Medical Center (QMC)
Hawaii Pacific Health (HPH)
Castle Medical Center
Shriners Hospitals for Children - Honolulu

Other (please specify)

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Has this protocol or proposal been or will it be submitted to any Institutional Review Board(s) or ethics review committees other than the UH IRB?				N
Is this a multi-site project? (A multi-site study is one where different PIs at different institutions are conducting the same study or aspects of the same study.)				N
If this study also involves site(s) outside UH, will UH function as the coordinating center or lead institution? (Check N/A for studies done solely at UH.)	**Yes**	**No**	X	**N/A**

Please attach any and all non-UH IRB approval correspondence or letters of permission / support from external study sites, if applicable, in the Attachment section.

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* * * General Checklist * * *

General Checklist

Select All That Apply, unless otherwise indicated :

Section 1: If you are requesting that UH cede IRB authority to another IRB, stop here, do not use this application. Instead, submit the following materials to the Human Studies Program Office at uhirb@hawaii.edu.

X Request to have UH IRB be the Relying IRB:

In addition to completing the application, please also include in the Attachment section the following required materials:

(1) Memorandum requesting to designate UH IRB as the relying IRB with justification
(2) IRB Authorization Agreement signed by the other institution's Institutional Official (template can be found by clicking the HELP button In the top right corner of this page)
.

Section 2: Biomedical Research

Industry-Sponsored Clinical Trial

Human blood, cells, tissues, or body fluids (Institutional BioSafety)

Tissues to be stored for future research projects

Tissues to be sent out of this institution as part of a research agreement (Material Transfer Agreement (MTA))

Human Embryos

Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.

Use of Patient related equipment? If Yes, specify what equipment is being used.

Radioisotopes/radiation-producing machines, even if standard of care (Radiation Safety)

Investigational Device

This study involves drugs or devices regulated by FDA

Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids).

Investigational drugs, reagents, or chemicals

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)

Section 3: Methodologies

Interview

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Questionnaire/Survey

Blood Draw

Section 4: For Student-led research

Thesis or Dissertation Project (Please upload proposal and dissertation/thesis committee approval (if available) in Attachments section.)

Class Project

Section 5: Other

This study is or will be posted on ClinicalTrials.gov

If checked, specify the number in the field to the right:

Protocol involves studying potentially addicting drugs.

Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.

HIPAA Authorization

Waiver or Alteration of Authorization

Activities Preparatory to Research

Limited Data Set and Data Use Agreement

Use and Disclosure of Decedents PHI without Authorization

Specify any other (use the text box to the right)

---

* * * Funding * * *

NONE--This project does not have any funding.
If you want to add Funding for the study, please uncheck "NONE."

Funding

Add external and internal grant funding source(s) below: Federal Government, Other Gov. (i.e., State, local), Foundation or Other. Select "None" above if there is no external funding for the study.

Funding from Infrastructure or Training Grant

Name of Funding Source(i.e.,name of Infrastructure or Training Grant)	CHS# of Infrastructure or Training Grant(118 Designation)	MyGrants Proposal Number
Subaward from University of Mass, Lowell		

Funding for this study has been secured by the UH Office of Research Services (ORS)

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* * * Application Type Checklist * * *

Application type checklist

Not Human Subjects Research/Undefined Research/Training or Infrastructure Grant

Exempt

X Expedited/Full Board

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* * * Expedited Paragraphs * * *

PLEASE READ: For Expedited Review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.

Select the following applicable categories to determine if your research project qualifies under Expedited Review. If none of the categories are applicable to your research project, a Full Committee Review will be required. For Expedited or Full Review, proceed to complete the following application.If none of the expedited criteria are appropriate for your project, please move to the next screen WITHOUT checking any of these criteria; your protocol will be reviewed by the full IRB. Note: The IRB will make the final determination if your protocol is eligible for expedited review.

Select one or more of the following paragraph(s):

Check all that apply	Category	Description
	1a.	Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
	1b.	Research on medical devices for which
		i) An investigational device exemption application (21 CFR Part 812) is not required; or
		ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
	2a.	From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
	2b.	From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
	3a.	Hair and nail clippings in a non-disfiguring manner;
	3b.	Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
	3c.	Permanent teeth if routine patient care indicates a need for extraction;
	3d.	Excreta and external secretions (including sweat);
	3e.	Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
	3f.	Placenta removed at delivery;
	3g.	Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

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	3h.	Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
	3i.	Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
	3j.	Sputum collected after saline mist nebulization.
	4a.	Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
	4b.	Weighing or testing sensory acuity;
	4c.	Magnetic resonance imaging;
	4d.	Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
	4e.	Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
	5.	Research involving materials (data, documents, records, or specimen) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
	6.	Collection of data from voice, video, digital, or image recordings made for research purposes.
	7.	Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects - 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

	8a.	Research permanently closed to enrollment of new subjects, all subjects have completed all interventions, and research remains active only for long term follow up of subjects.
	8b.	Where no subjects have been enrolled and no additional risks have been identified
	8c.	Where remaining research activities are limited to data analysis
	9.	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has previously determined that the research involves no greater than minimal risk and no additional risks have been identified.

---

* * * Summary, Purpose, Procedures * * *

Title (Please indicate if the protocol title is different from the proposal title)

Reducing Head Impact Exposure in Hawaiian Football Players and Enhancing Community Awareness and Environment for Head-Safety

Proposed Start Date: 05/27/2019 **Proposed End Date:** 05/01/2023

1. Summary

a) **Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.**

High school football participants are reported to sustain an average of 600, and as many as 2000, head impacts in a single season. Impacts to the top and front of the helmet generate the greatest forces, and thus pose the highest risk for acute brain and spinal cord

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injury. Equally disconcerting is the potential relationship between the accumulation of concussive and sub-concussive impacts (head impact exposure, HIE) and the risk for developing long-term conditions such as cognitive impairment, early-onset Alzheimer's, and chronic traumatic encephalopathy (CTE). Tackling and blocking behaviors using the head as the point of first contact can be attributed, in part, to the fact that players wear a helmet, which influences behavior by increasing the perception of safety. Thus, our Central Hypothesis is: an evidence-based helmetless tackling and blocking (HuTT®) program can decrease the risk of acute head and neck injury while minimizing potential adverse effects on developmental cognitive trajectories in this vulnerable population. The study will be conducted using a pre-test, post-test quasi experimental research design with football players (~200) recruited from two to three high school football teams in Oahu, Hawaii. The variables will be measured over three years, spanning three separate fall football seasons.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.

Thus, our Long Term Goal is to reduce head and neck injury in football. Our Central Hypothesis is: a football player who regularly practices tackling and blocking drills without a helmet in a controlled environment will naturally leave his head out of contact and is likely to continue to do so while wearing the helmet during games and full-contact practices. This learned motor behavior will reduce the number of head impacts football players sustain throughout their playing career and thus reduce their risk of acute and chronic head and neck injury. We will test our Central Hypothesis with the following Specific Aims:

Specific Aim 1: Evaluate the efficacy of a novel helmetless tackling intervention in Hawaiian high school football. Hypothesis: Football athletes that receive the intervention will have reduced frequency and magnitude (eg linear acceleration) of helmet impacts compared to the control group as measured by a head impact measurement system.

Specific Aim 2: To study the relationship between impact biomechanics and clinical outcomes in high school football. Hypothesis: Due to fewer head impacts, the intervention group will demonstrate improved outcomes in neuropsychological and self-report symptoms scores in post season evaluations compared to the control group.

Specific Aim 3. Evaluate the self-efficacy of players and coaches for achieving and reinforcing head-protective behaviors during tackling and blocking. Demonstrating the intended improvement in player and coach self-efficacy will be achieved by comparing data from novel Tackling and Blocking Appraisal and Coaching Appraisal inventories administered both immediately before and after the season. Hypothesis: Participants and coaches assigned to the HuTT® intervention will improve self-efficacy scores for head-protective behaviors compared to controls.

Outcomes: We expect a reduction in HIE and concussions in our research participants, improved clinical outcomes, and stronger self-efficacy for head-safe behaviors. These outcomes can serve as the platform to support sustained implementation beyond the initial research teams, as well as a wider acceptance in other schools and playing levels (e.g., youth football) throughout Hawaii. Ultimately, our Long Term Goal is to improve the cognitive trajectory for children playing football in Hawaii by reducing HIE and risk for long term impairment, such as CTE, which aligns with the mission of the Gary O Galiher Foundation.

b) What do the investigators hope to learn from this project?

The investigators expect a reduction in HIE and concussions in our research participants, improved clinical outcomes, and stronger self-efficacy for head-safe behaviors. These outcomes can serve as the platform to support sustained implementation beyond the initial research teams, as well as a wider acceptance in other schools and playing levels (e.g., youth football) throughout Hawaii. Ultimately, our Long Term Goal is to improve the cognitive trajectory for children playing football in Hawaii by reducing HIE and risk for long term impairment, such as CTE, which aligns with the mission of the Gary O Galiher Foundation.

3. Procedures

a) Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.

Prior to the start of preseason, the players (and their legal guardians) will be informed of the purpose of the study, the requirements, and its associated risks and benefits and then sign an approved informed consent/assent form. Following documentation of informed consent/assent, all athletes will be fitted with a new Riddell helmet also outfitted with an in-helmet head impact sensor. The helmet with the sensor will be worn in all practices and games and used to record the location and magnitude of all impacts sustained on the field. As part of the pre-season baseline assessment for concussion, all athletes complete a baseline Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT®) test. The ImPACT® test will be administered again at the conclusion of the season (~week 13). This timeline will be repeated in years two and three. Head (TBI, mTBI, concussion) and serious neck injuries will be tracked as they normally would and treated according to current recommendations15 throughout the course of each season.

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The HuTT® program, created by a PI Swartz, emphasizes proper tackling and blocking technique using closely supervised drills where players participate without their helmets and shoulder pads in place.14 Helmetless tackling and blocking training is the element that is inherent to HuTT® and reinforces the behavior of going into contact without initiating contact with the head. The HuTT® program is modeled after a basic tackling drill set-up familiar to the sport of football, but performed without helmets. Drills will be supervised at all times. Feedback will be provided to confirm proper technique as well as to immediately correct improper technique. The HuTT® drill will be completed during warm-up and takes approximately 5-8 minutes. The primary investigator, and experienced designees, will train coaches in the HuTT® technique. The HuTT® program is deliverable as an on-line application to provide asynchronous textual and video content. Coaches can conveniently review videos of drills on their smart phones. Subjects in the intervention groups will participate in HuTT® 4 times per week throughout the pre-season and regular season. The control groups will participate in football as normal.

i) **Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.**

Student athletes in Hawaii participate in the ImPACT testing annually as part of standard care.
The HuTT program is experimental.

b) **Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).**

Data will be collected in person and over the course of a football season. The intervention, The HuTT® drill, will be completed during warm-up and takes approximately 5-8 minutes.The primary investigator, and experienced designees, will train coaches in the HuTT® technique. Subjects in the intervention groups will participate in HuTT® 4 times per week throughout the pre-season and regular season. The control groups will participate in football as normal. Data will be collected by the PI and co-PIs.

i) **Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.**

The HuTT® program is deliverable as an on-line application to provide asynchronous textual and video content.

c) **For school-based activities where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and nonsubjects will be located during the activities.**

NA - this will take place in an extracurricular activity

d) **State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section**

N/A

e) **Will audio or video taping of individuals occur? Will photographs of individuals be taken? Describe what will become of the tapes/photographs (e.g., shown at scientific meetings, erased, etc.).**

Yes there will be video taping of the football drills. No photographs will be taken of individuals. The video recordings will help coaches with feedback and review of drills. The videos will be stored on a safe database and erased after the completion of the study.

f) **Will the proposed research involve the use of existing data/specimens? If so, check all that apply:**

- i. **The research involves data from publicly available sources**
- ii. **That data will be recorded by the investigator in such a manner that subjects cannot be identified.**
- iii. **Any link to identifying information has been destroyed**
- X iv. **N/A**

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* * * Background and additional procedures * * *

4. Background and additional procedures

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a. Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.

The Evolution of Protective Headgear in American Football, its Benefits and Consequences
Historically, participants in American football (whose origins come from rugby) did not wear, nor were they required to wear, any type of head protection. In 1939 rules changes required head protection, but the head protection used at that time were nothing like modern day helmets, and afforded little protection against anything other than minor injuries, such as lacerations. The design of football helmets evolved in the 1950s and into the 60s from a leather cover to a helmet composed of a solid outer shell with a harness or webbing on the interior. Further changes in the late 1960s and 1970s saw the interior of the helmet incorporate padding and, eventually, air bladders. These helmet design changes were designed to mitigate and distribute the forces associated with head impacts and greatly reduced the incidence traumatic brain injuries and deaths. However, the incidence of direct fatalities in football climbed during the late 1960s and early 1970s as tackling with the head (spearing) became more common as a result of the hard outer shell of the helmet. Rules changes to eliminate intentional spearing reduced the incidence of catastrophic head and neck injuries1. However, despite efforts directed towards improving helmet design and rules, catastrophic head and neck injuries remains a problem to this day.2 Due to this continued concern, and in particular the reported long-term cognitive deficits that have been linked to both repeated concussions and football participation3-5, helmet manufacturers have introduced yet more design changes and newer materials into their helmets. The standards that helmet manufacturers adhere to, set forth by the National Operating Committee on Standards for Athletic Equipment are not expected to result in prevention of concussions. Thus, improving helmet design and materials are not resolving the issue at hand; impacts to the head and the forces transmitted to the brain.

Tackling Without a Helmet
At all levels of play, impacts to the head occur frequently and often exceed 90g of linear acceleration6-9. Logic dictates that avoiding head impacts will reduce the risk of these injuries. It is unrealistic to expect that there are any measures that could be taken to completely eliminate head impacts in football without changing the fundamental nature of the sport. However, it is widely accepted that the helmet enables participants to more willingly sustain head contact during play because of the protection it affords. This phenomenon, known as 'risk compensation', has been attributed to injury and behavior indices in several sports.10, 11 In vivo data using the Head Impact Telemetry System during non-contact, or 'shells', practices in collegiate football players revealed they experienced head impact accelerations that were higher than those they experienced in games.9 These findings have also been observed on the high school level.12 In these so-called non-contact practices, players continue to make head to head contact with teammates during drills as the helmet is the only protective gear worn. Indeed, if the football participant were not wearing a helmet, it is unlikely that they would choose, or allow, their head to be involved in the impact during tackling or blocking, much less initiate contact at this point. Tackling without a helmet is common in others sports, with rugby serving as the most recognized example. Head and neck injury and concussions are common in rugby, but what is absent from the literature are reports of deliberate head to head hits or the head being used as the point of contact during the tackle. Undeniably, without any form of protective headgear one is more likely to reflexively avoid making contact with the head during a tackle. In fact, a study that investigated the effects of protective headgear in rugby not only found that it did not reduce the risk for head injury or concussion, but the researchers report evidence that wearing headgear was associated with a higher incidence of injuries than those not wearing padded headgear.13 Due to the nature of the sport of American football, particularly in that it involves a great deal of incidental head contact with opponents and the ground, removing the protective helmet entirely would increase risk of traumatic head and brain injury. However, there is no regulation that prevents a football player from practicing blocking and tackling without a helmet to solidify a proper technique which naturally and appropriately leaves the head out of the tackle. Our prior research on the collegiate level provides early evidence support proof-of-concept for this approach.14 Therefore, the Purpose of our study is to evaluate the effectiveness of a helmet-less, tackling training (the HuTT® Technique) intervention for head impact prevention in high school football participants from Hawaii.

b. Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).

Sample Size Determination
Power calculations for unpooled t-tests for the mean differences between the treatment and control groups were conducted using PROC POWER in SAS (version 9.4). The power calculations were performed for the target sample size (75 in both the treatment and control groups) and an approximation of the sample size in year three. The sample size in year three is partially accounted for 20 players graduating and 5 players lost to attrition (e.g., moving to a different school) or lack of compliance. Both sets of power calculations used an alpha of 0.05. The difference in the mean and standard deviation varied from 0.5 to 4 and 2 to 4, respectively.

At the conclusion of each season all raw impacts recorded by the head impact system and ImPACT scores for each player will be reduced by UH Co-I's and the graduate assistant(s) into spreadsheet format, coded, and sent to Co-I Heavner (statistician), who will be blinded to participant group assignment. Dr Heavner will produce all relevant outcome variables (e.g., impact location, linear acceleration, symptoms scores, etc.) and then import this data into a separate software package for statistical analysis. Subjects must have participated in at least 60% of the exposures and HuTT® sessions in a year in order to be considered to be in compliance for the study. To control for differences between players in the opportunities to sustain head impacts, contact exposures will be calculated for each player based on participation in practices and games. Days lost to injury will be tracked. For Specific Aim #1 a

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between-subjects ANOVA will be used to head impact biomechanics (frequency, force, location). For Specific Aim #2 a between-subjects ANOVA will be used to compare scores on the ImPACT test (memory composite (verbal and visual), visual motor speed composite, reaction time composite and symptoms scores) at baseline, mid-and post-test between the groups. Significant interactions and main effects will be followed up with appropriate t-tests with Bonferonni corrections.

c. **Alternative Procedures. Describe any alternatives to participating in the research. (e.g., standard of care treatment, etc.). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.**

NA

d. **Will subjects be followed after their active participation is complete?** N

If yes, explain why and describe how:

e. **Will subjects have access to the study treatment/procedure after completing the study?** N

If yes, explain why and describe how:

f. **Do any of the following apply.**

i. **Will subjects be audio recorded?** N

ii. **Will subjects be videotaped?** Y

iii. **Will subjects be photographed?** N

If yes to i, ii or iii, explain the collection process and use in the context of this research of such media

The HuTT® program is deliverable as an on-line application to provide asynchronous textual and video content. Coaches can conveniently review videos of drills on their smart phones to provide feedback. Videos may also be used as part of procedural integrity of intervention.

(Explicit consent must be obtained for use of these methods for Expedited and Full Board studies.)

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* * * Subject Population (a-f) * * *

5. Subject Population

a) **How many subjects do you intend to enroll and/or how many subject records do you intend to access?**

i. **At this site**

# of subjects 0

# of records 0

ii. **At all sites** N/A

# of subjects 375

# of records 375

b) **Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)**

i. **Identify inclusion criteria.**

Participants will be included if they are on the selected high school football teams. Teams participating are St Louis High

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School Junior Varsity and Varsity Football teams, Roosevelt High School Junior Varsity and Varsity Football teams, Kalani High School Junior varsity and Varsity Football teams, and Pac-5 (Mid Pacific Institute, Maryknoll Schools, University Lab, Assets schools, Pacific Baptist, Island Pacific Academy, Christian Academy, Pacific Buddhist Academy, Hanalani Schools) Varsity football.

ii. Identify exclusion criteria.

Students who are not part of the football team will be excluded from the study.

c) What is the rationale for studying the requested group(s) of participants?

The study is based on a football tackling and blocking program so the participants would need to be part of the football program as it will be implemented in practices.

d) If your participants include pregnant women, human fetuses, neonates, children, adults with diminished capacity, and/or prisoners, describe the protocol-specific safeguards used to protect the rights and welfare of this study population:

Confidentiality: We seek to maintain the confidentiality of all data and records associated with your participation in this research. Each subject will be given a unique identification code, and data will be observed and tracked using the SIM™ device (described earlier) and password protected, cloud-based storage via proprietary software (Triax Technologies, Inc.). The unique identification code allows data to be stored without direct identifiers. Personal information will be kept on a password protected computer, to which only the PI and co-PIs will have access. Any paper documentation containing codes and/or corresponding personal information collected during this research will be stored in a locked filing cabinet.

Any pictures and/or video recordings that become necessary for reporting and/or instructional purposes will be handled in the same way as data. All records and documentation will be kept for 3 years after completion of the study and will be destroyed at the end of this time. The results of this study will be used in reports, presentations, and publications and the data will be reported as an aggregate and in summary. As such, there is no way an individual participant will be identified.

Participation is strictly voluntary: If you refuse to participate, neither you will not experience any penalty or negative consequences. If you participate in this project and you later want to change your mind, you may withdraw at any time during the study without penalty.

e) Provide a clear compelling rational for excluding women, minorities, or minors, if they are intentionally excluded from the research. X **N/A**

f) State if any of the subjects are students, employees, or laboratory personnel. Please explain how subjects will be protected from coercion and undue influence **N/A**

The consent and assent forms will explicitly state that participation is strictly voluntary. If you refuse to participate, neither you will not experience any penalty or negative consequences. If you participate in this project and you later want to change your mind, you may withdraw at any time during the study without penalty. Participation or non participation in this project will not have any effect on playing time, team status, etc.

g) Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training). Also, explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research (e.g., differences with U.S. culture).

While working with students with disabilities during his matriculation as an undergraduate and graduate student, I would noticed that the little things students with disabilities accomplished were milestones whether it be education, play, social interaction and quality of life. The simple joy of obtaining tasks that typical individuals take grant for was such a wonderful moment to experience. Thus led to my future goal to work and teach students with disabilities; inclusive within this area are students with traumatic brain injuries.
I had the unique opportunity to work directly with individuals at Ohio State who were on the cutting edge of developing robotic manipulations for individuals with traumatic brain injury and disabilities, leading me to develop a cognate in Special Education technology. Consequently, I continued to work with disabilities (not only traumatic brain injuries) but all disability types. Progressing in this area, I found that individuals with disabilities and traumatic brain injuries are diverse, unique and no two individuals may be alike. This led to two highlights: (1) developing a research focus on Single Subject Research (albeit Applied Behavior Analysis), and

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Collaboration. My single subject research line of inquiry was selected primarily since researching disabilities was not conducive in obtaining large sample sizes. Second, collaboration was another area of focus since each individual's unique and diverse needs required input and attention from other fields such as Occupational Therapy, Physical Therapy, School Psychology, other educators and parents.
At present, I am Professor and Chair of the Kinesiology and Rehabilitation Science department, College of Education, University of Hawaii at Manoa. In addition, to my chair duties I am the Principal Investigator (PI) for an OSEP Personnel Preparation Grant and PI for HCAMP which is currently being supported by State of Hawaii Law SB 2557 "Relating to Concussions." As the PI for HCAMP since 2010, I have the opportunity to work closely with colleagues such as Troy Furutani, Ross Oshiro, Dr. William Tsushima, Dr. Henry Lew, Dr. Jennifer King and others to strengthen concussion related education and awareness for individuals.

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* * * Subject Population (g-j) * * *

5. Subject Population

g) Will bilingual or multilingual subjects be recruited? N

h) Will non-English speaking subjects be recruited? N

If yes, state language(s) spoken (other than English):

i) Will subjects be less than 18 years of age? Y

Age Ranges:

0-7

8-13

X 14-17

j) Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire) in the Attachment Section (#16).

The students will be screen for participation in interscholastic athletics as required by their school and Interscholastic League of Honolulu and Oahu Interscholastic Association. Students who wish to participate in football are required to complete a pre participation physical exam, medical history, and be medically cleared by a licensed MD. The required forms are documented, stored, and property by the participating school. These requirements are the standard of Care for sports participation in high schools and required by every participating schools.

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* * * Recruitment Process, Subject Compensation and Costs * * *

6. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- **List any specific agencies or institutions that will provide access to prospective subjects.**
- **Identify who will contact prospective subjects and how.**

Once IRB is obtained, formal parental meetings will occur at each site. Erik Schwartz and Jay Myer from UMASS, Lowell will also be there to explain the HuTT system to parents. Principal investigators and co-investigators will be the primary individuals making initial contact with schools using flyers/posters, letters, and face to face interactions. After formal meetings and discussions, parents can provide consent and students can assent to participate. If parents/students are unable to attend face to face meetings and

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discussions, they will be informed of the research using flyers/posters, email communication (letters), and information on a web page. Parents will be invited to contact research personnel to ask questions. This allows sufficient time without duress before agreeing to participate. In this scenario, parents will have the opportunity to submit consent forms electronically via email attached document (docx, pdf). If parents/students elect not to participate, he will still be on a participating member of the football team. He would not be subjected to the helmet sensors within the new study provided football helmets.

b) Planned Subject Identification Methods:

	N/A		Direct advertising
	Chart/database review		Living conditions (e.g., nursing home residents)
	Class participants		From PI's own practice/clinic
	Organization mailing lists		UH Participant Recruitment Pool(e.g.,SONA)
	Circumstance (e.g., homelessness)		

If referrals, explain how much they will be compensated for referrals if compensation is given.

X Other (please specify): interscholastic team participants

c) Planned Recruitment Materials/Methods:

	N/A	X	Flyers/posters
	Phone Scripts		Letters to providers/schools/organizations
	Television ads		Newspaper ads
X	Letters to prospective subjects		Radio ads
	Oral Scripts		PowerPoint presentations
	Internet ads/postings		Email
X	Face to face interactions		UH Subject Pool
X	Other (please specify):		Web page

(All advertising must be submitted for review in its final printed/recorded form)

Note: Attach copies of ALL recruitment materials in the Attachment Section

7. Subject Compensation and Costs:

a) Will subjects receive compensation for participation? N

Total amount (in dollars or equivalent)

b) Form of Compensation:

	Cash		Voucher
	Check		Course/extra credit
	Gift card/certificate		Reimbursement only
	Other (please specify):		

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

d) If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they

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not wish to participate in the study.

e) Will subjects or their health care providers be required to pay for any study related procedures or products?

i. If yes, explain:

f) Who is responsible for costs incurred due to injury/harm?

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* * * Risks * * *

8. Risks

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) **PI's evaluation of the overall level of Risk. (Please check one: minimal or minimal.)**

X Minimal (everyday living)

Minimal (greater than everyday living)

b) **Describe all known risks or discomforts associated with study procedures whether physical, psychological or social (e.g., pain, stress, invasion of privacy, breach of confidentiality) noting probability and magnitude of potential harm. Specify the risk(s) associated with each research procedure or test.**

The potential study procedure risk in this study are minimal. Participants will be asked to wear the headband device within the football helmet (Ridell Speedflex) that may provide very minimal discomfort and participate in drills without a helmet and shoulder pads that are designed to reinforce proper technique when going into contact as during a tackle or block which may be different than they are used to. Furthermore, the risk for a breach of confidentiality is very minimal as all data storage is locked or password protected. Outside of the study procedures, the inherent risk when participating in tackle football include but not limited to musculoskeletal injuries, head injuries, neck injuries, and spinal injuries.

c) **Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).**

Participants can choose to participate in the study or not participate freely. They can also stop at any time without punishment.

We will seek to maintain the confidentiality of all data and records associated with your participation in this research. Each subject will be given a unique identification code, and data will be observed and tracked using the SIM™ device (described earlier) and password protected, cloud-based storage via proprietary software (Triax Technologies, Inc.). The unique identification code allows data to be stored without direct identifiers. Personal information will be kept on a password protected computer, to which only my postdoctoral research assistant or I will have access. Any paper documentation containing codes and/or corresponding personal information collected during this research will be stored in a locked filing cabinet. Any pictures and/or video recordings that become necessary for reporting and/or instructional purposes will be handled in the same way as data. All records and documentation will be kept for 3 years after completion of the study and will be destroyed at the end of this time. The results of this study will be used in reports, presentations, and publications and the data will be reported as an aggregate and in summary. As such, there is no way an individual participant will be identified.

d) **How will subjects be assessed for adverse events?**

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Through observation and communication with the participants and coaches/research site supervisors. Each team has certified athletic trainers at all practices and games.

e) **Is there a plan to monitor study data for subject safety?** N

If yes, discuss who will monitor the study data and describe the monitoring plan:

---

* * * Benefits * * *

9. Benefits

a) **Discuss any potential benefits that would justify involvement of subjects in this study. Compensation is not considered a benefit.**

i. **Direct benefits to subjects (if applicable)**

The direct benefits gained from participating in this study are minimal, and participants will not receive any compensation. However, participants be using a new helmet, will wear a head impact device that might be helpful in the diagnosis of a concussion, and if assigned to the intervention group, participants will be able to practice appropriate blocking and tackling techniques, which may benefit the individual by helping to avoid head impacts while participating in football. If participants are assigned to the control group, they will benefit from the additional focus on other football-related skills.

ii. **Indirect benefits to society**

If the techniques used in this study decrease the number and magnitude of impacts to the head, then participation in football could be safer for all participants if others adopt the technique. This can lead to fewer injuries and lower healthcare costs for the public.

b) **Explain how the potential benefits justify the potential risks involved in participation in this research.**

The benefits greatly outweigh the very minimal risks of this study. The risks only include possible discomfort from the headband and very outside chance of breach of confidentiality while the benefits include possible greater safety, new helmets, and better skills.

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* * * Procedures to Maintain Confidentiality * * *

10. Procedures to Maintain Confidentiality or Anonymity

Will your research involve any of the following types of data listed below? Y

Which of the following types of data will you work with:

Identifiable
Information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person or investigator could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, and place of employment).

Anonymous
Data are anonymous if no one, not even the researcher, can connect the data to the person who provided it--no identifying information is collected from the individual. Investigators must be aware, however, that even if no direct identifiers (name, address, student ID, etc.) are collected, identification of a participant may be possible from unique individual characteristics (indirect identifiers). For example, a participant who is a member of a certain ethnic group or who was studied because of distinctive personal accomplishments or medical history might be identifiable from even a large data pool.

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De-identified
If the dataset has been stripped of all identifying information and there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means). Note: This also applies if the source of the data is identifiable but the data collected is not.

X Coded
This refers to data that have been stripped of all direct subject identifiers, but in this case each record has its own study ID or code, which is linked to identifiable information such as name or medical record number. The linking file must be separate from the coded data set. This linking file may be held by someone on the study team (e.g. the PI) or it could be held by someone outside of the study team (e.g. researcher at another institution). A coded data set may include limited identifiers under HIPAA. Of note, the code itself may not contain identifiers such as subject initials or medical record number.

a) If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable.

b) Explain how you will protect subjects' privacy.
Note: Privacy refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interest's people want to control:

- The time and place where they give information.
- The nature of the information they give.
- The nature of the experiences that are given to them.
- Who receives and can use the information.

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center that is clearly identified as such by signs on the front of the building. Please keep this definition in mind as you respond to this item.

c) Describe how you will maintain the confidentiality of subjects' information.
Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.

Only the PI and co-PIs will have access to the data. We seek to maintain the confidentiality of all data and records associated with your participation in this research. Each subject will be given a unique identification code, and data will be observed and tracked using the SIM™ device (described earlier) and password protected, cloud-based storage via proprietary software (Triax Technologies, Inc.). The unique identification code allows data to be stored without direct identifiers. Personal information will be kept on a password protected computer, to which only the PI and co-PIs will have access. Any paper documentation containing codes and/or corresponding personal information collected during this research will be stored in a locked filing cabinet.

d) Who will have access to study records or specimens? (Please identify specific team members by name.)

Only the PI and co-PIs.

e) If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?
NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the IRB application submission. It includes data or specimens collected for research and non-research activities.

NA

f) How will subjects be asked to provide their permission for release of identifiable data collected as a part of this proposed research (e.g., pictures, recordings, responses to research questions), now or in future? Explain and include appropriate statements in consent materials.

No identifiable data will be released or kept. All recordings will be from a distance and there is no way that an individual participant

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can be identified.

g) **If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?**

NA

h) **If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.**

Each subject will be given a unique identification code, and data will be observed and tracked using the SIM™ device (described earlier) and password protected, cloud-based storage via proprietary software (Triax Technologies, Inc.). The unique identification code allows data to be stored without direct identifiers. Personal information will be kept on a password protected computer, to which only PI and co-PIs will have access. Any paper documentation containing codes and/or corresponding personal information collected during this research will be stored in a locked filing cabinet.

i) **Explain why, where, in what format, and for how long data/specimens will be retained.**

All records and documentation will be kept for 3 years after completion of the study and will be destroyed at the end of this time. Data will be kept for this length of time for analysis and reporting. The data will be stored via a password protected, cloud based storage, password protected computer, or locked filing cabinet.

---

* * * Consent Information * * *

11. Consent Information

11 a & b only apply to applications where no consent document is provided to research subjects.

a) **How will subjects be informed of procedures, intent of the study, and potential risks to them?**

b) **How will subjects be informed they may withdraw at any time without penalty?**

See sample consent forms at research.hawaii.edu/orc/human-studies/forms/#templates

c) **Click Add to answer consent process questions and provide the consent forms.**

Note: Attach, in the Attachments Section, written and/or verbal instructions the subject will receive.

Informed Consent

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Title	Consent Information Type	Attached Date
Consent	Consent	04/27/2019
Revised Consent	Consent	05/21/2019
Revised Consent 5/23/19	Consent	05/23/2019
Revised Consent 6/5/19	Consent	06/05/2019
Revised Consent 4/22/20	Consent	04/22/2020

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* * * Assent Background * * *

12. Assent Background

(Complete if applicable)

Assent Document: A form or script of the information that will be conveyed to the child about the study. In general, researcher must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of hildren, more than one assent form may be needed (i.e., an assent from suitable for a 17 year old is not usually suitable for a 7 year old child).

Assent Waiver: No child assent will be sought at all. This means that the IRB is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefits that is important to the health or well-being of the child.

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

See sample consent/assent forms at research.hawaii.edu/orc/human-studies/forms/#templates

Click Add to attach the Assent forms and provide assent process background information for each Assent Form, Alteration Form and Waiver.

Assent Background

Title	Assent Information Type	Attached Date
Assent	Assent Form	04/27/2019
Revised Assent	Assent Form	05/21/2019
Revised Assent 5/23/19	Assent Form	05/23/2019
Revised Assent 4/22/2020	Assent Form	04/22/2020

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* * * HIPAA * * *

13. Health Insurance Portability and Accountability Act (HIPAA)

If you are using PHI and this page is not active you must return to the General Checklist and check the box regarding the use of PHI in this research.

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without the person's authorization (i.e., IRB Waiver of HIPAA Requirement Authorization).

Research involving the use of PHI may require privacy board review to ensure thhe protocol satisfies HIPAA requirements. The UH IRB does not normally serve as a privacy board. If privacy board review is required, researchers will normally need to obtain this review separately from the IRB review.

For more information on UH HIPAA requirements and UH programs covered by UH HIPAA policy, please see: www.hawaii.edu/infosec/hipaa/

Model language for a HIPAA authorization document: HIPAA /Privacy Rule Authorization Template

Protected Health Information (PHI) is health information with one or more of the following identifiers. For more information consult HIPAA Privacy Rule for Research

Research which involves the use of de-identified data is exempt from HIPAA requirements. In order to be de-identified data. NONE of the subject identifiers listed below can be collected, used, reviewed, recoded, accessed or disclosed.

Please review the following list and indicate if any of the information will be collected from any medical records for the purpose of this research project.

1. Names
2. Social Security Numbers
3. Telephone Numbers
4. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census;
   - i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
   - ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
6. Fax Numbers
7. Electronic Mail Addresses
8. Medical Record Numbers
   - You must attach a data collection sheet identifying the data points being collected from the MRN
9. Health Plan Beneficiary Numbers
10. Account Numbers
11. Certificate/License Numbers
12. Vehicle Identifiers and Serial Numbers, including License Plate Numbers
13. Device Identifiers and Serial Numbers
14. Web Universal Resource Locations (URLs)
15. Internet Protocol (IP) Address Numbers

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16. Biometric Identifiers, including Finger and Voice Prints
17. Full Face Photographic Images and any Comparable Images
18. Any other unique identifying number, character, or code (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

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* * * Drugs and Devices * * *

14. Drugs and Devices

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* * * Potential Conflict of Interest * * *

15. Potential Conflict of Interestrr

Conflict of Interest and the definitions related to the Conflict of Interest Policy and the following questions, please refer to the Help Screen.

Conflict of Interest: Please check Yes or No for each item below.

a) N Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

b) N Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

c) N Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

d) N Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) N Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) N Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

Significant Financial Interest: Please check Yes or No for each item below.

g) N Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) N Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

Minimizing Risks and Disclosure to Subjects

i) N Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required

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to disclose all such conflicts to all research participants in the research consent form.

j) What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?

If you checked Yes to any statement (a-h, except f) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest.

By submitting this form, you are attesting that you have read the UH HRPP Policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Link to UH's Conflict of Interest Policy: research.hawaii.edu/orc/conflicts-of-interest/.

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* * * Attachments * * *

16. Attachments

Attach relevant documents here. These could include:

- NIH/ CITI Training Certificate
- Advertisements
- Bibliography
- Conflict of Interest Information
- Cooperating Institution(s) Approval
- Data Collection Sheet
- Explanatory diagram (Sequence of events)
- Grant proposal
- Impact Statement
- Information Sheets/Brochures
- Investigators Brochure
- Material Safety and Data Sheet
- Package Inserts
- Phone Scripts
- Program Project Grant/List
- Questionnaires
- Recruitment Material (e.g., flyers, e-mail text)
- Recruitment Statement
- Protocol
- Protocol Modification Requests
- Training Grant/List
- Other files associated with the protocol (you can upload most standard file formats: xls, pdf, jpg, tif, etc.)

Please be sure to attach all documents associated with your protocol. Failure to attach the files associated with the protocol may result in this protocol being returned to you for completion prior to being reviewed.

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Students: Be sure to attach the Methods section of your thesis or dissertation proposal. If this protocol is associated with a grant proposal, please remember to attach your grant.

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Other	citiCompletionReport_SocialBehavioral Research Conduct	04/28/2019	04/29/2019
Other	citiCompletionReportHSR	04/28/2019	04/29/2019
Other	citiCompletionReportIPS	04/28/2019	04/29/2019
Other	citiCompletionReportIPS_Basic	04/28/2019	04/29/2019
Other	citiCompletionReport2531474	04/29/2019	04/29/2019
Recruitment Material (e.g., flyers, e-mail text)	808HuTT Recruitment Flyer	06/26/2019	06/27/2019
Recruitment Material (e.g., flyers, e-mail text)	808HuTT Recruitment Letter	06/26/2019	06/27/2019
Recruitment Material (e.g., flyers, e-mail text)	808HuTT Link to Website	06/26/2019	06/27/2019
Protocol Amendments	Safety Plan form protocol ID 2019 00370	04/14/2021	04/14/2021
Protocol Amendments	HuTT COVID.mod.8.30.2021	08/30/2021	08/30/2021

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* * * Obligations * * *

Obligations

Obligations of the Principal Investigator include the following:

Provide all subjects a copy of the signed consent form, if applicable.

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes.

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel.Training must be updated every three (3) years.

Final Report - The IRB will be notified when the study is complete.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge. I agree to report any substantive changes to the information contained in this application immediately to the UH IRB.

I agree to not enroll any subjects or collect any data intended only for research use prior to issuance of an IRB approval.

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I understand that I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all of the applicable policies and regulations.

This study will not begin until the investigator receives written final approval or determination of exemption.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

Submit the Continuing Review Form in order to maintain active status of the approved protocol. This form must be submitted to the IRB at least 30 days (AHSIRB) or 45 days (SSIRB) prior to the date of expiration.

Submit the Protocol Violation Form to report protocol Deviations/Violations or the Event Reporting Form to report Adverse Events (AEs) or Unanticipated Problems that occur in the course of the protocol.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

"blue"Please click "Check for Completeness" to your left to continue to the next step. If the protocol is complete and ready for submission, please click "Submit Form" to your left to submit your protocol for IRB Review.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
04/23/2019	NEW FORM CREATED		
04/29/2019	NEW FORM SUBMITTED	Y	
05/01/2019	NEW FORM PANEL ASSIGNED		
05/01/2019	NEW FORM PANEL MANAGER REVIEW		
05/02/2019	NEW FORM PANEL REASSIGNED		
05/06/2019	NEW FORM REVIEWER(S) ASSIGNED		
05/06/2019	NEW FORM REVIEWER(S) ASSIGNED		
05/21/2019	NEW FORM REVIEWER(S) ASSIGNED		
05/22/2019	NEW FORM REVIEWER(S) ASSIGNED		
06/05/2019	NEW FORM APPROVED	Y	Y

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06/26/2019	AMENDMENT 1 FORM CREATED		
06/27/2019	AMENDMENT 1 FORM SUBMITTED	Y	
07/05/2019	AMENDMENT 1 FORM REVIEWER(S) ASSIGNED		
07/10/2019	AMENDMENT 1 FORM APPROVED	Y	Y
09/30/2019	AMENDMENT 2 FORM CREATED		
09/30/2019	AMENDMENT 2 FORM SUBMITTED	Y	
10/10/2019	AMENDMENT 2 FORM REVIEWER(S) ASSIGNED		
10/15/2019	AMENDMENT 2 FORM APPROVED	Y	Y
04/06/2020	CONTINUING REVIEW 1 FORM CREATED		
04/06/2020	CONTINUING REVIEW 1 FORM SUBMITTED	Y	
04/08/2020	CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED		
04/28/2020	CONTINUING REVIEW 1 FORM APPROVED	Y	Y
01/15/2021	CONTINUING REVIEW 2 FORM CREATED		
01/20/2021	CONTINUING REVIEW 2 FORM SUBMITTED	Y	
02/08/2021	CONTINUING REVIEW 2 FORM DELETED		
04/07/2021	CONTINUING REVIEW 3 FORM CREATED		
04/07/2021	CONTINUING REVIEW 3 FORM SUBMITTED	Y	
04/12/2021	CONTINUING REVIEW 3 FORM REVIEWER(S) ASSIGNED		

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04/14/2021	CONTINUING REVIEW 3 FORM APPROVED	Y	Y
04/22/2021	AMENDMENT 3 FORM CREATED		
04/22/2021	AMENDMENT 3 FORM SUBMITTED	Y	
05/10/2021	AMENDMENT 3 FORM REVIEWER(S) ASSIGNED		
05/10/2021	AMENDMENT 3 FORM REVIEWER(S) ASSIGNED		
05/18/2021	AMENDMENT 3 FORM APPROVED	Y	Y
05/18/2021	AMENDMENT 4 FORM CREATED		
05/18/2021	AMENDMENT 4 FORM SUBMITTED	Y	
06/04/2021	AMENDMENT 4 FORM REVIEWER(S) ASSIGNED		
07/01/2021	AMENDMENT 4 FORM APPROVED	Y	Y
08/30/2021	AMENDMENT 5 FORM CREATED		
08/30/2021	AMENDMENT 5 FORM SUBMITTED	Y	
09/08/2021	AMENDMENT 5 FORM REVIEWER(S) ASSIGNED		
09/15/2021	AMENDMENT 5 FORM APPROVED	Y	Y
01/25/2022	CONTINUING REVIEW 4 FORM CREATED		
02/09/2022	CONTINUING REVIEW 4 FORM SUBMITTED	Y	
02/09/2022	CONTINUING REVIEW 4 FORM REVIEWER(S) ASSIGNED		
02/21/2022	CONTINUING REVIEW 4 FORM APPROVED	Y	Y

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12/19/2022	CONTINUING REVIEW 5 FORM CREATED		
01/13/2023	CONTINUING REVIEW 5 FORM SUBMITTED	Y	
02/08/2023	CONTINUING REVIEW 5 FORM REVIEWER(S) ASSIGNED		
02/17/2023	CONTINUING REVIEW 5 FORM APPROVED	Y	Y