**PROTOCOL TITLE:**

One Team: Changing the Culture of Youth Sport

**NCT#:** STUDY00000972

**DATE:** 1/10/22

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## 1.0 Objectives

*1.1* Help community-based sports leagues to refine and optimize the structure and protocol for pre-game safety huddles so that they are acceptable and usable to all stakeholders.

Specific Aim 1: Refine the Pre-Game Safety Huddle (PGSH) intervention using a community-engaged approach working in partnership with key stakeholders (coaches, athletes, parents, referees, medical providers and league administrators) in two geographic regions.

Aim 1a: Pilot test the survey measures with key stakeholders to establish validity and feasibility.

Specific Aim 2: Evaluate delivery, fidelity and reach of the PGSH intervention, and explore factors associated with implementation quality.

Specific Aim 3: Conduct a pilot randomized controlled trial of the PGSH intervention in football and soccer leagues and examine primary outcomes of: (1) sportsmanship and (2) playing with concussive symptoms.

## 2.0 Background

*2.1* More than 1 million youth sustain a sport-related concussion (SRC) each year.[1] The middle school age range is particularly concerning because it is a time when children have both a unique susceptibility to brain injury[2] and high participation rates in organized sports with concussion risk, such as soccer and football.[3] There are two avenues to decrease this concussion risk: (1) **minimizing the number and force of collisions to decrease concussion incidence** (primary prevention) and (2) **improving concussion identification to decrease concussion morbidity** (secondary prevention). One promising strategy to address both primary and secondary prevention is rule changes, including: outlawing dangerous collisions and requiring that athletes with suspected concussion be removed from play. However, rules are ineffective if they are not enforced, and such enforcement requires not only support from officials, but also from coaches, parents, and athletes. In addition, because concussions are an invisible injury, removing concussed athletes from play requires athletes to report symptoms, and studies suggest 30-50% of athletes do not report them,[4] risking greater injury.[5] A primary barrier to decreasing concussion risk is the culture of youth sport, as highlighted in the Institute of Medicine report on concussion in youth sports.[6] Existing interventions have been siloed, targeting one group rather than the interconnected network of stakeholders that produce and maintain the culture of youth sport, and unsurprisingly such an approach has not been ineffective.[7] Equally problematic, prior interventions have not been designed to diffuse widely in low resource communities.[8] Preventing injury in youth requires shifting values, attitudes, norms and behaviors of all key stakeholders (coaches, parents, athletes, and referees) in order to engage communities towards a culture of sport safety. It is thus essential that such interventions be designed in a manner that either accommodates or is robust to difference

***2.2 Culture change is needed to reduce the health burden of concussion in youth sport.***

**Addressing concussion risk in youth sports is essential.** More than 44 million U.S. youth 6 to 17 years old participate in organized sports,[3] and every year more than one million of these youth are diagnosed with a concussion.[1] Sports that involve routine contact and collision pose the greatest risk for concussion, with soccer being the most popular and football yielding the highest rates of injury.[15] **Younger youth have greater vulnerability to concussion.** Myelination, or the development of an insulating sheath around neuronal white matter to improve the speed of neuronal transmission, peaks during the 7-13 year old age range[2] and unmyelinated axons are more sensitive to brain injury.[2,16–18] The impact of brain injury is further multiplied for youth, since cognitive deficits due to brain injury (attention, memory and executive function) can disrupt future

cognitive and psychosocial development.[6,19] **Low socioeconomic status youth often face additional risk factors.** Low SES youth are more likely to participate in certain high concussion-risk contact sports, such as football and boxing[20] and they have greater decreases in health-related quality of life following concussion.[21–23] The Institute of Medicine (IOM) report[6] on concussions in youth sport identified an urgent need to decrease the health burden of concussion in youth sport through primary and secondary prevention, and to reduce inequities in low SES populations. The IOM report additionally states that decreasing injury risk will require a change in the culture of youth sport.

**Primary prevention (decreasing concussion incidence) requires decreasing collisions.** There are two pathways towards decreasing concussion incidence in sports: (1) decreasing collisions and (2) mitigating the force of those collisions. The majority of sports-related concussions occur due to collisions between players, with the most dangerous type being head to head collisions.[24,25] Concussions are also more likely to occur when a player is unaware of an impending collision (such as when being hit from behind), potentially due to the inability to stabilize the head and neck.[26,27] **Rules related to potentially dangerous collisions can be an important strategy for improving safety, but they must be enforced.** There are a number of examples of rule changes that have reduced contact and collisions, such as outlawing "spearing" in football (i.e., initiating contact with the head and neck)[28,29] and outlawing tackling from behind in soccer. However, rules related to safety are not always enforced[29,30] and rule violating play is often a cause of injury.[31,32] Consistently enforced rules can change behavior due to the threat of sanction in the short-term, and also because of the ways in which we begin to adopt the moral code inherent in rules, such that not following them becomes internalized as unethical or wrong.[33] If coaches know that spearing will result in their athlete being ejected, they will teach their athletes to avoid spearing. The cost of spearing will not be worth the potential tactical benefit. Athletes in turn will refrain from spearing both to avoid reprisal from the coach, but also to prevent ejection from the game, as this is a meaningful consequence for them. **Referees face challenges to enforcing rules.** Youth sport referees are typically employed on a contract basis and are often covering teams with different levels of competitiveness and physical contact. In addition, referees must make judgment calls, such as whether a particular collision constitutes "dangerous play" or whether to call a minor foul in the penalty box, as this will result in a penalty kick (and thus may determine the outcome of the game). Coaches, parents and athletes can create an environment in which referees feel pressure to not consistently enforce rules.[34,35] Referees at the youth level are often young themselves, which may create power differentials relative to parents and coaches. If coaches, athletes, parents and referees are all on the same page when it comes to the importance of good sportsmanship (including adhering to rules and respecting referees), there should be less rule violating unsafe play and referees should feel more confident consistently enforcing rules related to safety.[35,36]

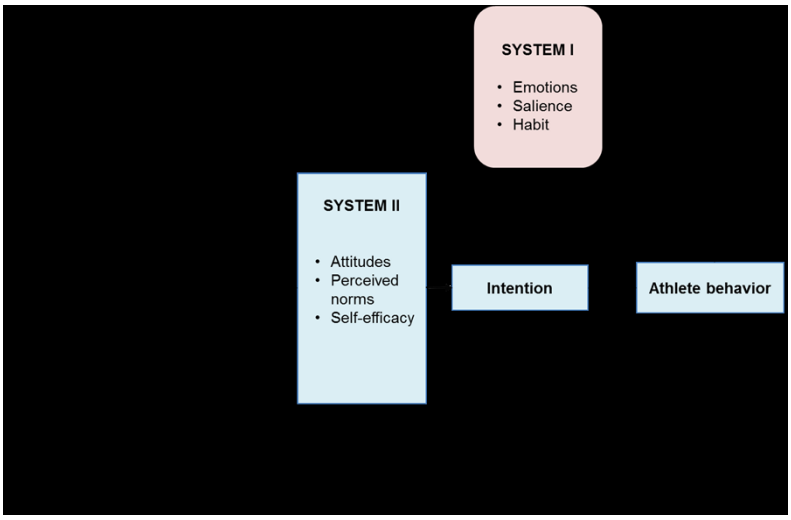
**Secondary prevention (decreasing concussion morbidity) requires improved concussion identification.** Athletes who delay care seeking tend to have a longer recovery time[37] and during the symptomatic period post-concussion the brain is in a vulnerable state during which an additional impact is likely to have magnified neurologic consequences.[5] **Even with rules about removal from play, athlete reporting still matters.** All states now have laws requiring athletes with a suspected concussion be removed from play. However, because symptoms of concussion (such as headache or difficulty concentrating) are not observable, early identification often relies on disclosure of symptoms to an referee, coach or parent.[38] As a result, many concussions go unreported and undiagnosed.[4,39] We must remember that athletes who are experiencing significant cognitive impairment due to injury may not be able to report symptoms. Thus, it is essential that coaches, athletes and parents are all aware of the symptoms of concussion and the risk of continuing to play, and are empowered to speak up if they think a concussion has occurred (i.e., "bystander" reporting).[40] Athletes play a particularly important role in this regard, as they are both the most familiar with and the most proximate to their teammates on the field.[40] **Interpersonal interactions and norms are key drivers of concussion reporting.** An athlete will not report a suspected concussion if they do not feel their coach, teammates or parents would want them to do so.[34,41–45] These perceptions are typically created through formal and informal interpersonal interactions.[35,41] For example, an athlete observing his coach yell at the referee for calling an injury timeout will be less likely to report their own injury. Although the opinions of peers matter to youth,[40] in the sport context coaches play a critical role in shaping team norms about seeking care for one's own concussion or speaking up about a teammate's injury.[34,44,46,47] Thus, good sportsmanship from everyone involved in youth sports— athletes, coaches and parents—is important for creating an environment in which looking out for concussion safety is seen as a valued behavior.

**Existing educational paradigms are not sufficient to reduce the risk of concussion in youth sport.** Increased public awareness of the risk of concussion in youth sports in response to concussion legislation, lawsuits and the media have fueled the development of multiple interventions aimed at decreasing concussion risk, primarily by increasing concussion knowledge.[48] However, these interventions have not been successful at changing the culture of sport.[7] **First, prior interventions have sought to educate stakeholder groups in silos**. Some of strongest drivers of behavior related to concussion safety are the product of the web of interconnected interpersonal interactions between youth sport stakeholders[34,40,42–45] There is thus a critical need to intervene at a systems level to address the behaviors between and within different stakeholder groups that shape the culture of youth sport. **Second, prior interventions have presumed that decisions about concussion during games were being made rationally and deliberately.** Sporting events tend to be characterized by physiologic arousal and strong emotions among coaches, athletes, parents, fans, and referees. In such conditions, decisions are less likely to be made deliberatively and more likely to be made using associative processes and in response to the immediate context,[49–51] or what has been described by Kahneman[52] as "System I" to distinguish it from slower rational thinking (System II). In such decisional environments, an individual's self-concept also has a powerful influence on their willingness to engage in target behaviors.[53] For example, if the individual views themselves as someone who values safety, they may be more likely to engage in safety supportive behaviors, such as reporting a potential concussion. **Third, prior interventions have been delivered during the pre-season and then forgotten.** Psychosocial-educational programming conducted at one time point rarely results in sustainable behavior change.[54] **Fourth, prior interventions have been difficult to disseminate and thus may have exacerbated health inequities.** Developing a complex psychosocial-educational intervention that requires substantial resources and programmatic support rarely leads to sustainable change. There is a large body of literature across domains about the failure of such interventions to result in broad-based dissemination and persistent impact.[55] Further, there is growing concern that inequitable diffusion and implementation of interventions can exacerbate health inequities.[56,57]

**Culture influences behavior.** The win-at-all-costs mentality that characterizes professional sport is present in many youth sport contexts.[58] Behaviors that reinforce the value of winning rather more than the value of safety, such as playing through injury, have been identified as a threat to healthy youth sport participation among both boys and girls.[59] Youth sport is influenced by broader culture messages about what it means to be an athlete, and the culture of a team or youth sport organization is the product of the values, norms and interpersonal interactions in that unique context[60–62] (Figure 1). Team values do not necessarily reflect the values of all team members, but they provide a guide for the types of action viewed as desirable by the group.[63,64]

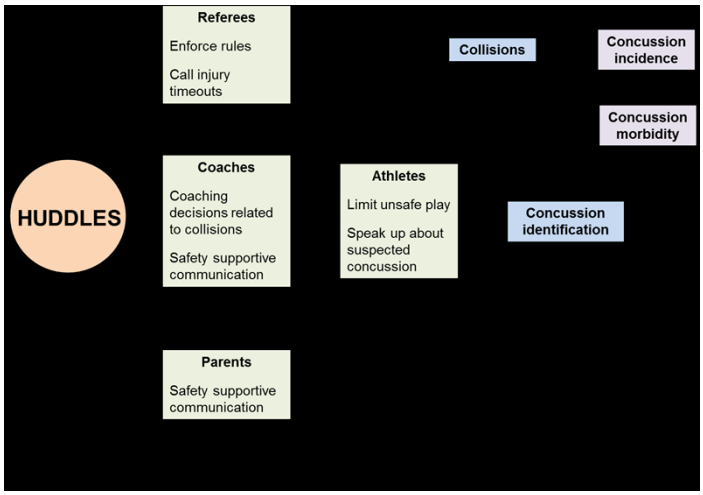
Although teams can espouse certain values, they only influence behavior if they are substantiated by actions consistent with those values. For example, a youth football organization may state that they value fun and safety, however if rules related to safety (e.g., outlawing spearing or other dangerous collisions) are not enforced, or if coaches and teammates discourage athletes from reporting concussion symptoms, the stated organizational "value" will be undermined and another value (e.g., winning at all costs) will be assumed and adopted. Team values and norms influence behavior by providing information about the potential social costs or benefits of performing specific behaviors.[65,66] If an athlete thinks their teammates and coach care about safety (value) and would want them to speak up if they think they have a concussion (norm), they are more likely to speak up. **Values must be salient to influence behavior.** During a game teams hold simultaneous competing values (i.e., safety vs. winning), and the more strongly the value of safety is activated, the more likely it will influence behavior.[64,67] Appraisals about the salience of a value often occur through a reactive or emotional process (System I), Amidst intense game play, athletes are unlikely to make deliberative (System II) decisions, and instead are likely responding out of emotion, habit and salience (Figure 2).[52] Reinforcing values of safety before the game with key stakeholders and ensuring that interpersonal interactions are supportive of safety should make all involved more likely to behave in a safe manner. **Culture change in youth sport can have implications across the lifespan.** Long-held attitudes and beliefs about toughness and playing through injury reinforced in multiple contexts over time can be difficult to change. The benefit of injuryrelated intervention at younger ages is that it can have a lasting impact on risk-related attitudes and behaviors.[68] The 9-13 year age range is a particularly promising window for intervention as athletes are at a stage of cognitive development where they can think abstractly about risk and injury,[69] but not old enough that attitudes are immutable.[70]

**Conceptual framework.** We propose a conceptual framework for understanding the relationship between context, culture, and athlete behavior related to concussion safety (Figure 2). In this model individual actions both produce and are the product of the social and structural contexts in which they are embedded.[60,71] In other words, structural factors such as policies and community-varying resources influence team culture, and team culture in turn shapes athlete behavior. In this model there are two pathways through which individuals make decisions about whether or not to engage in a specific safetyrelated behavior: a reactive or emotional pathway (System I) and a deliberative pathway that involves rational expectancy value calculations (System II).[52] Prior studies on concussion safety-related behavior have typically used deliberative theories such as the Theory of Planned Behavior[72] to understanding behavior and inform intervention design. However such approaches are flawed as they do not capture the reactive and emotional processes (System I) that are often at work when decisions are made under stress or pressure. Moreover, System I type processes are more likely to be influenced by team norms, as they require quick decision making. We have thus adapted the Integrated Behavioral Model[73] to include both System I and System II decisional pathways to elucidate the influence of context and culture on individual behaviors.




**Huddles provide a simple and evidence-based method facilitating culture change within groups.** The football huddle was invented in 1894 by quarterback Paul D. Hubbard, to provide a means for communication protected from the opponent. More recently huddles have been adapted by the medical system as a way to unify key stakeholders towards a goal of changing the culture of safety.[9,74] In the medical context, huddles are brief meetings of personnel prior to complex medical events (the start of a clinic day, prior to surgery), with a goal of ensuring that all members of the team are sensitized to safety priorities. Huddles have been found to improve the sense of teamwork,[75] increase desired outcomes, and significantly decrease medical errors.[9] The Institute for Healthcare Improvement has recommended the huddle as a means for improving efficiency of care and decreasing negative outcomes. Qualitative data suggests medical safety huddles achieve changes in safety culture by: (1) creating time and space for communication, (2) reaffirming shared values and (3) strengthening relationships.[76]

**Huddles as a foundation for culture change in youth sport.** Our goal is to adapt huddles back to the sports field as a means for reinforcing safety on the playing field, applying the principles of culture change from medical safety huddles. Huddles have the potential to influence both deliberate (System II) and reactive (System I) decision making. We believe the combination of engaging positively with the other team and affirming shared values regarding safe sport will motivate coaches and athletes to follow the rules of the game. We hypothesize that this will then be reinforced by referees' behavior as they will be more likely to enforce the rules when given the explicit support of key stakeholders (particularly coaches and parents). With contextual cues supporting following the rules, fewer illegal collisions will occur, resulting in decreased concussions. In addition, support for speaking up about a potential concussive injury (or calling an injury time-out in the case of the referee) will create new norms about concussive



reporting, and make it more likely that athletes will speak up about potential injury, whether sustained by themselves or by a teammate, thus decreasing concussion morbidity.

## 3.0 Inclusion and Exclusion Criteria

3.1 Eligibility Screening

Community-based sports organizations that are interested in implementing the pre-game safety huddles will be eligible for inclusion in the sample. Within teams in these organizations, individuals will be eligible for participation if they choose to implement a pre-game safety huddle.

*3.2 Inclusion and Exclusion Criteria*

Inclusion: Referees, coaches, youth athletes, medical providers and/or parents in one of the participating leagues or clubs are eligible for inclusion in the study.

3.3 Special Populations

- Adults unable to consent –excluded
- Individuals who are not yet adults (infants, children, teenagers) – Referees who have not yet turned 18 and youth athletes (ages 8-17) are eligible for inclusion.
- Wards of the state – excluded
- Pregnant women – eligible for inclusion if they are a sport stakeholder  Prisoners – excluded

## 4.0 Study-Wide Number of Subjects

- Aim 1: Approximately 122 interviewees (parents, coaches, athletes, referees, medical providers). Fifty huddle leaders who will be recorded giving a huddle. Unknown number of participants who give very brief feedback on huddle feasibility and acceptability and unknown number of huddle participants being observed; number of subjects in participating leagues cannot be approximated given that it's unknown how many people will participate and will be observed to participate in the huddles.
- Aim 1a.: Approximately 30 participants in cognitive interviews about survey questions and 900 survey participants (athletes and parents)
- Aim 2: Approximately 80 interviewees (parents, coaches, athletes) + approximately 120 referees and coaches submitting post-game huddle surveys. Fifty huddle leaders who will be recorded giving a huddle. Unknown number of huddle participants being observed and invited to give brief feedback; number of subjects in participating leagues cannot be approximated given that it's unknown how many people will be observed to participate in the huddles.
- Aim 3: Approximately 350 athletes, 350 parents, 25 coaches

## 5.0 Study-Wide Recruitment Methods

- Across all three aims, our recruitment process will occur at two levels. At the first level, sports leagues and clubs will be recruited to participate in huddles and to allow the voluntary participation of their referees, medical providers, athletes and coaches in data collection. Next, individuals (coaches, athletes, parents, referees, medical providers) will be given the option of participating in the huddles and data collection.
- Aim 1: We will approach leagues and clubs to invite participation in safety huddles using a key informant led snowball sampling process. Our sports league partners (USA Football and US Soccer) and our community partners in the Seattle and southern Georgia regions will help provide referrals and recommendations of individuals we should be in contact with to invite league and club level recruitment. Subsequently, when a given league or club has decided to implement safety huddles as part of their league's concussion education efforts, then coaches, parents, referees, medical providers and athletes who are

affiliated with that league will be sent information about the huddles, and then subsequently will be invited to provide feedback about the huddle to help with its improvement. Huddle leaders and huddle participants will be approached before, during, or after games where a rapid pilot trial occurred, at the game location, and asked if they would allow their huddle message to be recorded or to provide feedback about the safety huddle.

- Aim 1a: Some of these individuals on sports teams participating in Aim 1, as well as youth athletes who are not participating in huddles, will also be invited to pilot test the survey measures**.** This will occur in two steps. First, approximately 30 stakeholders (parents, coaches, youth athletes) will be asked to provide feedback on provisional survey measures using a cognitive interviewing process in which they read through measures and let us know if they make sense or what changes they would suggest to make the measures more useful. Based on this feedback, we will refine the survey questions and then recruit sport stakeholders (parents, youth athletes, coaches) to complete a written pilot test of the survey measures. Participants may be given a subset or a reordered version of the survey questions. These will be distributed in the manner that is most acceptable to the population either online, hosted on an online survey platform or in pen and pencil format. Recruitment will occur through an email invitation being forwarded by a league administrator or relevant leadership to their email distribution list for the relevant stakeholder group, along with information sheets. Stakeholders will then be provided with either an anonymous link to an online survey or a hard copy version of the survey at an in person meeting time (e.g., at an existing team or league meeting). In both formats, no names or other identifiers will be collected.
- Aim 2: We will approach leagues to invite participation in safety huddles using the same methods as in Aim 1, but with a different request as participating leagues (or divisions within leagues) will be randomized to either the huddle intervention or control condition. When a given league has agreed to allow its members to participate in the study, coaches, parents, referees, medical providers, and athletes who are affiliated with that league will be invited to provide feedback about huddle implementation (assuming the league is randomized to the intervention). Huddle leaders and huddle participants will be approached before, during, or after games where huddles were implemented and asked if they would allow their huddle message to be recorded and/ or to provide feedback about the safety huddle. Huddle leaders will provide their permission prior to any huddle being recorded and study staff will announce when recording begins. Referees and coaches will also be invited to provide game-level feedback, a post-game survey, about whether or not a huddle occurred by responding to a text, phone call or email from research staff. They will be invited to participate in this modality of data collection through the email invitation being forwarded by a league administrator to their email distribution list and/or at an in-person meeting attended by our research staff.
- Aim 3: Leagues that participate in Aim 3 will be a subset of those that participate in Aim 2, but data collection will be more intensive for selected teams as it will occur 2-3 times during the season via self-report surveys. Participants may be given a subset or a reordered version of the survey questions. Within each participating league, 3- 4 teams will be randomly selected and a team representative (coach or parent) will be approached to determine interest in participating in the more intensive part of the study. If a team is not interested, the next team will be approached. Parents, coaches, and athletes who are affiliated with that league will then be asked to participate in the study by completing three surveys, with an email describing this process sent via email by league administrators or study staff and a subsequent inperson invitation at the time of in-person data collection. Data collection will also be available online, and individual recruitment to participate in this modality will occur via an email forwarded by league administrators or the team representative.

5.2 Describe materials that will be used to recruit subjects.

Aim 1:

- Aim 1 FAQ
- Aim 1 Athlete Assent for Huddle Interviews
- Aim 1 Athlete Assent for Measure Piloting- Surveys and Interviews
- Aim 1 Email to Coaches Referees Medical Providers
- Aim 1 Information Sheet to Coaches Referees Medical Providers
- Aim 1 Email to Parents Athletes
- Aim 1 Information Sheet to Parents Athletes Aim 1a:
- Aim 1a Athlete Assent for Measure Piloting-Interviews Only
- Aim 1a Athlete Assent for Measure Piloting-Surveys Only
- Aim 1a Email to Parents Athletes
- Aim 1a Email to Coaches
- Aim 1a Info Sheet for Measure Piloting to Coaches
- Aim 1a Info Sheet to Parents Athletes

The initial contact with leagues and clubs will be made by email (FAQ). Once leagues and/or clubs have agreed to hold huddles, individual members (e.g., coaches, parents, youth athletes) will be recruited in a two-step process. First, an email introduction from leadership or study staff will be sent, along with an information sheet, informing stakeholders about the study, the huddles, and how to individually opt out. Then, we will be present in person to obtain feedback about huddles or survey measures, and at this point in time we will also answer any questions they may have and provide potential participants with a an information sheet about the study / assent Sheet .

Aim 2:

- Aim 2-3 FAQ
- Aim 2 Athlete Assent for Interview
- Aim 2-3 Email Intervention to Coaches
- Aim 2-3 Information Sheet to Coaches
- Aim 2-3 Email Intervention to Medical Providers
- Aim 2-3 Information Sheet to Medical Providers
- Aim 2-3 Email Intervention to Parents Athletes
- Aim 2-3 Information Sheet to Parents Athletes
- Aim 2-3 Email Intervention to Referees
- Aim 2-3 Information Sheet to Referees

Recruitment of leagues will occur in a similar manner as in Aim 1 with a similar email, adjusted to describe the different ask in Aims 2 and 3 (i.e., leagues will be randomized and data collection will be more intensive). Individuals will again be recruited in-person for interviews and post-game surveys, following an email introduction. Information sheets about the study will also be provided to them along with the email and in-person when recruiting individuals. When we recruit in person, we will also answer any questions they may have and provide potential participants with an information sheet about the study / assent sheet Aim 3:

- Aim 3 Athlete Assent Control for 3 Surveys

- Aim 3 Athlete Assent Intervention for 3 Surveys
- Aim 3 Email Control to Parents Coaches Athletes Referees and Medical Providers for Surveys

Recruitment of leagues will occur in Aim 2, but as described above will occur with a subset of the teams randomized to each arm, as data collection is more intensive for these teams. Recruitment of teams and individuals is described above. We will utilize an email and information sheet to describe the study to the coaches, parents, athletes. If athletes belong to a team that is selected as one of the teams with more intensive data collection, we will provide athletes with an assent sheet specific to that activity. Leagues/divisions in the control condition will also distribute an email recruiting teams for the surveys at three different time points.

## 6.0 Multi-Site Research

6.1 This is a multi-site study, currently occurring in Oregon, Washington and Georgia. Additional data collection and huddle piloting might take place at US Soccer-sponsored tournaments. Seattle Children's will act as both the main site and the coordinating center for Oregon and Georgia, however partners in Oregon and Georgia will have their own IRB review.

- Shared folders will be created to ensure all sites have the most up-todate protocol, consent and recruitment materials.
- Other sites will be required to submit IRB approval documents (initial approval, continuing review and modifications) to their IRB as the study progresses. Additionally, these will be monitored by the research coordinator at the Seattle Children's Research Institute
- Protocols will be designed to ensure confidentiality and security of subject data. We will minimize the use of identifiers and will de-identify data whenever possible. Files will not be shared with identifiable subject information across sites without ensuring that the file is password protected.
- Site visits will also occur a minimum of annually, with a particular focus on data management and security.
- Oversight regarding study protocols, progress, and data collection will also occur via periodic video conferencing calls with other study sites. Initially these will be very frequent (weekly), but may be changed to less frequent (monthly) when study protocols are well-established.
- Rules regarding study participation, including any concerns about non-compliance or confidentiality leaks will be outlined for study sites and a timely means for communication of any concerns will be described.

## 7.0 Study Timelines

7.1

- Aim 1: 2018 sports seasons. Subjects will only be asked to participate in feedback about huddles and survey measures and will not need to be involved longitudinally.
- Aim 2: Spring 2019 and fall 2019 youth sports seasons. Parents, athletes, medical providers, coaches and referees will be asked to participate for one season.
- Aim 3: Simultaneous and following Aim 2. Parents, athletes, medical providers, coaches and referees will be asked to participate for one season.

Data analysis and manuscript preparation will be completed 2020-2021.

## 8.0 Study Endpoints

8.1 Aim 1: This part of the study will be complete when we have a) a Finalized Safety Huddle Structure, b) Safety Huddle instructional materials for al key stakeholders, c) Pilot tested survey measures. Aim 2: This part of the study will be complete when all qualitative data
collection is finished and quantitative data analysis is complete. Aim 3: This part of the study will be complete when all survey data collection is finished and quantitative data analysis is complete.

8.2 The study involves no more than minimal risk so there are no pre-specified safety endpoints.

## 9.0 Procedures Involved

9.1 Study Design

**1. Aim 1**

Aim 1 will refine the content and structure of Safety Huddles. This will be accomplished by leagues choosing to implement a Safety Huddle structure recommended by the study team (e.g., huddle leaders state "Let's all have fun out there and play safe. It's on all of us to make sure no one plays with a concussion."). The huddle will address two main safety topics, and huddle leaders will be responsible for leading the affirmation of the two safety messages:

1. Affirm a collective commitment to sportsmanship (i.e., not engaging in dangerous and illegal collisions)
2. Affirm a collective responsibility that no athlete play while concussed

These huddles will occur prior to the start of games. Piloting will be carried out with local youth teams (ages 8-17) in three geographic regions (Washington, Oregon and Georgia) and in both males and females. Partner leagues will contact their constituents to find clubs and coaches willing to participate in huddle development. We will then coordinate with interested coaches to schedule a trial of the Safety Huddle at a game. Once we have identified a potential game for a Safety Huddle trial, referee and the head coaches of both teams will be contacted to explain the motivation behind Safety Huddles and instruct them on their role. At this stage we will also provide informational materials about Safety Huddles for their review. The role of the referee will be to initiate the huddle (i.e., gather the participants into the huddle). Coaches or other huddle leaders will be asked to take the lead on discussing the key topics: (1) collective commitment to good sportsmanship (including following the rules related to dangerous collisions) and (2) collective responsibility to make sure that no athlete plays while concussed. Coaches will also be responsible for informing athletes and parents that the huddle will occur prior to game day, and explaining its purpose. A research assistant (or a few research assistants) will attend the huddle pilot to record and observe the huddle, collect observational data, and support implementation as necessary. In the case that a huddle is selected to be recorded, the research assistant will announce beforehand that the huddle will be recorded, ensuring to capture the announcement on the recording. Following each rapid pilot trial we will invite participants (at least one huddle participant from each stakeholder group, i.e. referees, coaches, athletes, parents, and medical providers, if present) to give feedback about the huddles. Some participants will be invited to give brief feedback about the acceptability and feasibility of the huddles. For select stakeholders, they will be invited to participate in a more extensive one-onone interview or invited to contact us or give us permission to contact them to schedule a more extensive interview; we expect to conduct approximately 100 such interviews either in-person or over the phone, digitally audio-recorded and transcribed verbatim. Interviews will be designed to explore stakeholder perspectives regarding the Safety Huddles, with a focus on eliciting suggestions for improvement to the huddle content and structure. Guided by the Consolidated Framework for Implementation Research (CIFR),[14] core areas of focus will be: stakeholders' subjective experience with the huddles, perceptions about the complexity of the huddles and perceptions about the utility of huddles. We will also seek information on how stakeholders adapted the huddle concept to their local preferences, or how they think they could be adapted in the future. Qualitative interviews will be conducted by trained interviewers in each region who have experience working with youth sport stakeholders. We will bring this feedback to our community advisory board and research team and make modifications of Safety Huddle content and/or structure for subsequent implementation.

**1.2 Aim 1a**

In Aim 1a participating athletes and other relevant stakeholders from Aim 1 as well as those who will only be piloting measures, totaling approximately 30 stakeholders (parents, coaches, youth athletes) will be asked to provide feedback on provisional survey measures using a cognitive interviewing process. They will read through measures and let us know if they make sense or what changes they would suggest to make the measures more useful. The interviewer will use a cognitive interview guide that may change iteratively in order to maximize the utility of the qualitative data collected. This process will be recorded and transcribed. Based on their feedback and subsequent analysis, we will refine the survey questions. Then, we will recruit sport stakeholders (parents, youth athletes, coaches) to complete an anonymous written pilot test of the survey measures. These will be distributed in the manner that is most acceptable to the group- either online, hosted on an online survey platform such as Qualtrics© or REDCap or in pen and pencil format.

**1.3. Huddle instructional information.** We have developed a brief one-page instructional flyer about the huddle structure (see attached huddle instructional sheet) and similar information will be provided in a number of modalities, on-line, in-person and via video recordings. All materials will include: 1) The purpose of the Safety Huddles 2) Methods for completing the huddle 3) Huddle roles (i.e., referee as initiator, coaches as leaders, athletes and parents as representatives of their respective groups) 4) Topics (i.e, a) adhering to standards of sportsmanship and b) the necessity of reporting concussive symptoms). In our qualitative interviews with Huddle participants we will also query them about the Huddle instructional materials so as to make revisions to make them more useful.

**2. Aim 2**

The intervention will be rolled out using the final procedural details and huddle instructional materials developed in Aim 1. The intervention will be implemented at the league level in partner leagues in Washington, Oregon and/or Georgia.

**Data collection overview.** We will utilize a mixed-methods approach that includes 1) a review of referee and coach post-game surveys to quantify implementation reach and fidelity, and 2) qualitative data and interviews with huddle intervention participants to explore barriers and facilitators to implementation.

**Post-game surveys**. After every game, referees and coaches will be asked to answer a brief subset of questions about huddle implementation along the lines of: 1) Did the huddle occur; 2) Did you affirm support for rules related to concussion safety; 3) Did you affirm collective responsibility to make sure no athlete plays while concussed? 4) Were helmets worn? 5) Were both teams in the huddle? etc.This will be via phone, text, or on-line survey.

**Qualitative data collection**. Research assistants (RAs) will randomly select a game from one of the intervention divisions using digital number generation, and will attend the game. They will observe the Safety Huddle (see attached materials- Observation Guide) and then will approach Safety Huddle participants following the game to arrange a time to participate in an interview about their experiences with the huddle. In the case that a huddle is selected to be recorded, the research assistant will announce beforehand that the huddle will be recorded, ensuring to capture the announcement on the recording. The interviews will be semi-structured, based on a guide that may change iteratively in order to maximize the utility of the qualitative data collected, and will be conducted by a trained interviewer. They will either occur in-person or on the phone. We expect they will take approximately 45 - 60 minutes. We expect to conduct approximately 80 such interviews. All interviews will be digitally recorded and transcribed for subsequent analysis. Guided by the Consolidated Framework for Implementation Research,[14] core areas of focus for these interviews will be: the role of each key stakeholder in implementation (athlete, parent, coach, referee, and medical provider, if present), and the role of within-group communication. We will also conduct a series of interviews following completion of the intervention. We will explore all aspects of communication including formal processes (e.g., email, team meetings) and informal conversations between and within stakeholder groups (e.g., between teammates, between coaches and athletes, between coaches and parents, and between parents and athletes). We will also explore additional barriers and facilitators to implementation as participants raise them. Interview participants will also answer a series of brief closed-ended demographic questions (age, gender, sport, team, race/ethnicity) (see attached for a qualitative interview guide).

## 3. Aim 3

**3.1. Sample and recruitment.** We will utilize the same divisions randomized into the intervention arm in Aim 3 in Seattle as data will be collected during the same time period as Aim 2, (or following data collection for Aim 2) but will focus on a subset of teams. We will randomly select 3-4 teams from each participating league to receive: (1) greater support regarding the PGSH intervention to ensure fidelity of implementation, and (2) data collection using in-person surveys at three time points (preseason, mid-season and end of season). We will also randomly select another division within each stratum to serve as control. Teams in the control condition will not receive the PGSH intervention. Within control divisions we will randomly select 3-4 teams for the same survey data collection as teams in the intervention condition. We will contact the coach of randomly selected intervention and control teams to consent to participation. If a coach is unwilling to participate, we will contact the next randomly selected team. In practice, two matched divisions will be identified and teams within divisions randomly selected to participate prior to the division-level randomization process so that teams agreeing to participate are doing so before they know the condition to which they will be randomized. This process of stratification and random selection will ensure that teams in the intervention and control conditions within each strata are matched by age, sport, gender and region. We expect to recruit a total of 15-25 teams. Participants will be athletes, parents and coaches recruited from each of these teams. Based on estimates regarding team size, we anticipate that our sample will include a total of 300-400 athletes.

**3.2. Intervention and control conditions.** Teams in divisions randomized to the intervention condition will receive The PGSH intervention, which consists of Pre-Game Safety Huddles, as described previously. Control teams will be offered the opportunity to participate in the PGSH intervention in the year following our data collection.

**3.4. Measuring fidelity of intervention.** We will support teams to complete Safety Huddles during the intervention by sending automated text or email reminders to coaches and referees prior to each game. Coaches will indicate their preferred modality for reminders and provide their cell phone number and email address during baseline data collection. Following the game, coaches will then asked the post-game survey questions inquiring whether a Safety Huddle occurred. They will continue to receive up to three reminders to respond. Data will be analyzed using intent-to-treat, and thus teams will be retained in the sample regardless of huddle implementation. We will conduct sensitivity analyses looking at differences in outcomes based on Safety Huddle implementation.

**3.5. Data collection**. Parents, athletes and coaches will complete self-report surveys at three time points (pre-season, mid-season and end of season, see attached). For football, we will only have stakeholders complete these at two time points (pre-season and end of season) as the season is shorter than soccer. After the huddle leaders' first huddle, as part of pre-season data collection, we will utilize a subset of survey questions to find out how confident coaches are leading huddles and what athletes think about them. For each survey administration where study staff are present, snacks will be provided to the teams as a thank you. We will utilize paper surveys distributed at either games or practices by the research coordinator, as our previous work with sports organizations has suggested this is the most effective means to obtain representative data.[86,82,87] We will provide the option for parents, athletes or coaches who were not at the game or practice to complete the survey online, on the secure and mobile accessible Qualtrics© / REDCap survey platform. Based on our pilot testing we expect that the surveys will take about 5-10 minutes to complete. After the third administration of surveys, as a thank you, survey staff will provide pizza for those in attendance at the practice/ game.

**3.7. Summary of data to be collected for each aim:**

- **Aim 1**: responses to requests for huddle feedback, cognitive interviews, and qualitative interviews of athletes, coaches, parents and referees completed in-person or over the phone, audio-recorded and transcribed and anonymous surveys completed by a subset of league participants to validate surveys to be used in subsequent study aims.

- **Aim 2**: Referee and coach post-game surveys (an average of 3 questions) completed online or via text/phone after each game, qualitative interviews similar to those in Aim 1, and huddle audio recordings.
- **Aim 3**: Self-report surveys completed by parents, coaches, and athletes at three time points (pre-season, mid-season and post-season) and coach postgame surveys on huddle implementation

| Survey | Pre-season | Mid-season | Post-season |
|---|---|---|---|
| **Demographics (child/parent)** | x | x | x |
| **Concussion screen (child/parent)** | x | x | x |
| **Behavioral intention measures (child/parent)** | x | x | x |

## 10.0 Data and Specimen Banking

□ N/A

## 11.0 Data Analysis/Management

Aims 1 and 2:

**Qualitative data analysis.** Data will be analyzed using a Thematic Analysis[85] approach and coding for emergent themes with a minimum of two coders trained in qualitative methodology. Coding will be iterative and adjusted based on coder discussion. Coded segments will be entered in a de-identified fashion into Dedoose™ to facilitate analysis. Together with the advisory board, research staff will review emergent themes to triangulate and contextualize findings.

Aim 2:

**Quantitative analysis.** Following the guidance of Proctor and colleagues[83] for analyzing implementation data from systems-level interventions, we will conduct a multilevel analysis. We will use a cross-classified multilevel structure where games at level-1 are nested within both teams and referees as separate level-2 units. Implementation will be modeled as a two-part variable:[84] a binary outcome of whether or not a huddle occurred, and conditional on occurrence, its fidelity to intervention design. The cross-classified design will allow us to disentangle the relative importance of teams versus referees (using the Intra-class Correlation Coefficient; ICC) in explaining whether a huddle occurred and implementation quality. We will include fixed effects for the relative contribution of team attributes (sport, gender, age, SES and region) and referee attributes (age, gender, years experience) on implementation and implementation quality. We will include fixed and random linear and quadratic effects of time to examine evolving trends in implementation across the season (i.e., whether the probability or quality of implementation changed as a function of time), and the degree to which these trends varied across teams and referees (ICC).

Aim 3:

**Measures overview.** We will measure incidence of diagnosed concussions via self-report, but we do not expect to see differences in this outcome given the size of our study. The Pre-Game Safety Huddle intervention is designed to influence concussion risk behaviors, as these are proximal to concussion risk, specifically: (1) reporting of concussive symptoms and (2) sportsmanship (i.e., the likelihood of engaging in rule-violating potentially injurious play). We will measure both *expectations* about engaging in these concussion risk behaviors and *performed* athlete behavior (via self-report). Our primary outcome will be *expected likelihood of* reporting concussion symptoms, assessed using a validated measure developed during preliminary work for this study, Concussion Reporting Expectations (CR-E). Our secondary outcome will be athlete expectations regarding engaging in potentially Injurious Play (IP-E). We will also measure performed concussion reporting behavior (i.e., instances where an athlete sustained an injury and experienced symptoms that might have been a concussion, and then chose whether or not to report). We will include several other exploratory secondary measures:

- Athlete perception of coach norms regarding concussion reporting
- Athlete perception of coach norms regarding injurious play
- Athlete report of Youth sport values
- Athlete expectations regarding bystander reporting of potential concussion
- Athlete report on Prosocial and Antisocial Behavior in Sport Scale (PABSS)
- Acceptability of Intervention Measure (AIM-2)
- Feasiblity of Intervention Measure (FIM-2)

**Quantitative analysis.** Differences by study arm will be assessed using Pearson's chi-squared tests. Mixed effects linear regression models will be used to estimate the difference in CR-E score between intervention and control groups at the season-end time-point. Exploratory analyses by sport, sex and age will also conducted, using a separate model for each subgroup. All analyses will be adjusted for factors identified a priori or which appeared to vary between groups at baseline, including coach sex and age, team sex, youth age, and baseline score. Nested clustering by sport and team is accounted for via random effects (except when analyses were instead stratified by the corresponding variable). Generalized linear models with a log link and robust variance estimator will be used to estimate relative risks (RRs) and 95% confidence intervals (CIs) of the expected likelihood of engaging in a risky behavior in the intervention group relative to the control group at each follow-up comparison point. Clustering by team will be accounted for using a modified-sandwich robust variance estimator for cluster-correlated data. All models will be adjusted for baseline response, coach sex and age, team sex, and youth age (except in cases where analyses were stratified by the corresponding variable). Similar to CR-E, additional analyses will be stratified by sport and sex. Intervention effect on behavior will be explored among the subset of athletes who reported a blow to the head using a similar analytic approach as described above for likelihood of engaging in injurious play (IP-E).

## 12.0 Confidentiality

12.1

- Data from the study will be derived from patient responses to interviews, recordings, self-report surveys and observation. All data will be collected specifically for research purposes.
- Interviews/ Recordings: Transcribed audio-recorded huddles and individual interviews will be de-identified and stored online in a password protected file accessible only to the study team; a numeric code will be used to link audio-interviews to sport and game.
- Surveys: All study materials will be stored online in a password protected folder managed by the principal investigator. In Aim 1a (measure piloting), all survey data will be collected anonymously. In Aim 3, athletes will write their name on the first page of the first survey (to be detached from the rest of the

survey upon completion) and each participant will create their own study ID by answering the following questions:

- Date of birth (two numbers, for example, write 09 if you were born on the 9th): ___ ___
- Second letter of your last name: _____ o Number of siblings (write 0 if you have none): _____

Participants will be asked the same questions at each time point to track measure completion. Names gathered from the first time point will only be used if an athlete has a missing survey to facilitate later survey completion. The link between the names, study IDs and team name will be stored in separate password protected file.

- Hard copy surveys will be entered into Qualtrics©/ REDCap, an online survey platform. Until such point as this entering has taken place, surveys will be stored in a locked filing cabinet. After the research study concludes, we will close the Qualtrics© / REDCap account for this study, ensuring that all information is downloaded and subsequently deleted, to ensure that the data does not live in perpetuity 'in the cloud' on a vendor system. Further, after the study is closed and data has been downloaded and then subsequently deleted, we will confirm with Qualtrics© / REDCap that the account is closed and the data and respective account deleted and deactivated. All other study documentation will be retained for five years.
- No presentation or publication arising from this research will use subject names or other information that would allow subjects to be identified

12.2 Describe how data and specimens will be managed study-wide

- Data will be managed by the primary research coordinator for the study at the Center for Child Health Behavior and Development in the Seattle Children's Research Institute using survey management software.
- Survey and test data will either be stored in HIPAA compliant computers and servers or in locked file cabinets
- Data will be kept for 5 years after completion of the study.  Only the study team will have access to the data.

## 13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

13.1

 This is a low risk study and thus we do not anticipate any safety related issues with subjects due to the study. The primary risk to subjects is in regard to confidentiality, and we will discuss that in the confidentiality section below.

## 14.0 Withdrawal of Subjects

This study involves no more than minimal risks to subjects. Participants will be informed in the consent and assent process that they are welcome to discontinue participation at any time without penalty. We will not ask any subjects to withdraw.

## 15.0 Risks to Subjects and protection against risks

This study involves no more than minimal risks to subjects. The primary risks to the study include:

1) **Confidentiality:** For Aim 1a (measure piloting), for participants who only take surveys, this data will all be collected anonymously, as we will not collect any personal identifiers. Because it will be collected anonymously and no identifiers will be collected, it will not be possible for responses to be tracked back to any individual.
2) We will collect subject names and contact information for those who will receive an incentive for their participation, as per the requirements of the use of Clincard (see sections 9 and 23). We will also collect subject names and contact information for Aims 2 and 3. We will also collect audio recordings of subjects for qualitative analysis. These all contain PHI. We will use measures to ensure confidentiality of subjects (see Section 12).
3) **Distress or fatigue:** We will ask subjects to participate in interviews and surveys, and this may cause distress or fatigue. Participation is voluntary and subjects can discontinue participation at any time. Subjects can also skip any questions that they like.

## 16.0 Potential Benefits to Subjects

There is no anticipated direct benefit to participants, but our goal is that this research will make sports safer for all youth. Small incentives will be provided (see section 9).

## 17.0 Vulnerable Populations

- Parents who are pregnant will not be excluded from the research as it is minimal risk. The research does involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects. The research does not hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit to both the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus. The research also does not hold out the prospect of a direct benefit to the fetus, enroll children who are pregnant, nor will researchers have any part in discussing pregnancy viability or termination.
- This research involves children/adolescents who have not attained the legal age of consent. We believe that it presents minimal risk to children/adolescents as it involves asking them about their perceptions of a concussion education program that is meant to help inform them about a common injury in their sport and that aims to help keep them safe.

## 18.0 Community-Based Participatory Research

18.1

We have already begun discussions in the community regarding the study to ensure engagement and success with this approach. We will involve an Advisory board in a more formal manner in Aim 1 as we develop the huddle structure. The advisory board will consist of key stakeholders in local sports, and will provide input regarding huddle format and huddle instructional materials. The Advisory board will only be provided summary or de-identified data. We will meet with members of the advisory board regularly.

## 19.0 Sharing of Results with Subjects

Preliminary results of the study will be shared with subjects at the end of the season in a group manner, if teams request such information.

## 20.0 Setting

20.1 Describe the sites or locations where your research team will conduct the research.

- We will have three primary sites: Washington, Oregon and Georgia. The Washington site will provide coordination to the other two sites via the Seattle Children's Research Institute.
- Data collection will occur on the play field with youth sports teams participating in the PGSH study in any of the three regions

- We will have community advisory boards in Washington and Georgia, including athletes, coaches, parents, referees, sports organization administrators, and clinicians who provide medical care to concussed youth.
- For research conducted outside of the organization and its affiliates describe:
  - Data will be collected in Georgia and Oregon (as well as potential additional sites) in a manner identical to that in Washington.
  - We will utilize shared protocols and materials for all three sites.
  - We will request that the IRB in Georgia and Oregon review the study to ensure compliance with any internal specifications.

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## 21.0 Resources Available

### 21.1 RESEARCH TEAM:

The research team at the Seattle site consists of two PIs who both have extensive experience in concussion research. Their work focuses on concussion knowledge, attitudes and behaviors in youth and young adult sport settings and on developing an evidence base for diagnosis and management of this complex injury. They are knowledgeable about current and past pediatric concussion projects and studies and will contribute 20% of their time for the duration of the study.

We also have co-investigators in Georgia and Oregon, who are also very experienced in the concussion field and will help monitor research activities in those locations, with oversight from the Seattle Team. The co-I in Georgia will be managing recruitment and data collection in the Georgia region. Our co-I in Oregon will be managing recruitment and data collection in the Oregon region.

We are also working with a co-I with a PhD in Psychometrics who will be supporting the analysis piece of the grant from our Seattle location. Other team members will include a CRAII and an RA, who will help manage the project, assist with recruiting and retaining leagues and stakeholders, and collect and analyze data. We will also have some graduate students working in Georgia, and technologic support from the University of Oregon to build the materials. Additional hourly RAs and undergraduate volunteers may be employed as needed to assist with data collection.

All individuals working on this study will be required to complete appropriate IRB training such as CITI training and will be instructed with regard to ethical conduct of research and the importance of confidentiality by the co-PIs specifically.

## 22.0 Prior Approvals N/A

## 23.0 Recruitment Methods

Recruitment methods will be identical for all sites. Please refer to site-wide recruitment.

**Incentives for Aim 1:** All individuals who complete semi-structured, long-form qualitative interviews will be provided a $20 Clincard.

**Incentives for Aim 1a:** All individuals who complete cognitive interviews will be provided a $20 Clincard.

**Incentives for Aim 2:** All individuals who complete qualitative interviews will be provided a $40 Clincard.

**Incentives for Aim 3:** N/A

## 24.0 Use of Social Media

N/A

## 25.0 Local Number of Subjects

- Aim 1: 69 WA interviewees (parents, coaches, athletes) and 20 huddle leader recordings
- Aim 1a: 20 participants in cognitive interviews and 600 WA survey participants (athletes and parents)
- Aim 2: 40 WA interviewees (parents, coaches, athletes), 30 huddle leader recordings, + 60 WA Referees and coaches submitting Post-game huddle surveys
- Aim 3: (All will take place in WA) 660 athletes, 660 parents, 36 coaches

## 26.0 Provisions to Protect the Privacy Interests of Subjects

26.1 Participants in Aim 1 and Aim 1a will provide contact information if they agree to participate in a cognitive or long qualitative interview. Participants in Aim 3 will be asked to provide contact information as data collection is longitudinal. Participants will always be provided with an option to complete data collection either on the phone or via an online survey link so as to not have to complete the study activities in a public setting.

26.2 All research is voluntary. Subjects may choose not to participate at any time and may also choose to participate but not complete certain questions.

26.3 Data collected (including audio-recordings and surveys) will be stored in a de-identified manner for analysis. Contact information will only be accessed by staff needing to contact a study subject.

## 27.0 Compensation for Research-Related Injury

This study involves no more than minimal risk.

## 28.0 Economic Burden to Subjects

There are no costs anticipated to be associated with participation.

## 29.0 Consent Process

We are requesting a Waiver of Written Documentation of Consent, Waiver of Consent/Assent & Parental Permission, Waiver of Parental Permission, and HIPAA Waiver of Authorization as the study involves no more than minimal risk.

**Non-English Speaking Subjects**

The emails, the information sheets, and educational materials for parents will be translated into Spanish. Athletes, referees, coaches, and medical providers are all expected to be English-Speaking, therefore the translation of materials will only be done into Spanish and for the activities that a parent will be involved in. **Consent process:**

Aims 1, 2 and 3: We will ask athletic administrators or other representatives of leagues or clubs choosing to participate in the study to send an email informing all key stakeholders in their league (youth, parents, coaches, medical providers, and referees) about the PGSH study, the trialing of pre-game Safety Huddles and the planned data collection. This email will also include information about how to opt-out of participating in or giving feedback about huddles. In some cases depending on an organization's established communication channels, coaches may be asked to forward the email to their team and other stakeholders, such as the other team and/or referees. Coaches, medical providers, and referees will receive an information sheet about their own participation in data collection (e.g., surveys and/or qualitative interviews). Parents will receive an information sheet about their own and their child's potential participation. Participants will then be provided with a hard copy information sheet when approached for data collection in person. Youth athletes will at that point review a written assent form and provide verbal assent.

**Detailed description of consenting process:**
Aim 1: An information sheet will be distributed to parents, athletes, medical providers, coaches, and referees by the participating leagues by email or in hard copy format, depending on typical mode of information delivery to that stakeholder group by the respective league (or club) and preferences for communication. This information sheet will describe huddles and the nature of the research study (e.g., obtaining qualitative feedback about huddles and making adaptations to their content/delivery and pilot testing survey measures) and contact information for the study team (see Information Sheets for Aim 1). The email to the coaches, referees, and medical providers includes language for how to opt out of all study activities and that participation is voluntary. The introductory email to parents will state that if parents do not want their child to participate in the huddles, have a huddle recorded that their child would be participating in, participate in a post-huddle qualitative interview, or to provide feedback about the huddle, that they should contact the principal investigators of the study at the contact information listed on the sheet. Names of children who are not eligible to participate will be stored by the principal investigator in a password-protected file. The study team member responsible for data collection at a given team will be provided the list of children who are not eligible to participate, and these children, in addition to any children who do not provide assent, will not be eligible for the study. At games, if it's a huddle that will be recorded, the research assistant will announce beforehand that the huddle will be recorded, ensuring to capture the announcement on the recording. Subsequently, when stakeholders are approached in person at a game or practice they will be asked to provide an affirmative consent or assent to participate and be offered at written copy of the information sheet with study team contact information. Athlete participants will review an assent sheet and provide verbal assent (see Athlete Assent Sheets). For Aim 1a, an email, along with information sheets, and, subsequently, assent sheets will be distributed to potential subjects that would only be piloting measures, not participating in huddles. When approached, they will be asked to provide an affirmative consent or assent to participate
Aims 2 and 3: For the intervention arm, an information sheet will be distributed to parents, coaches and referees by the participating leagues by email or in hard copy format, depending on typical mode of information delivery to that stakeholder group by the respective league and league preferences for communication. This information sheet will describe huddles and the nature of the research study (the interviews to obtain feedback about huddles to assess their acceptability and implementation, the huddle recordings, and/or the surveys that will collect data about the efficacy of huddles in changing knowledge, attitudes and behavior related to concussion safety) and contact information for the study team (see Aim 2-3 Information Sheets). The individual emails to the coaches, referees, and medical providers includes language for how to opt out of all study activities and that participation is voluntary. The introductory email to parents will state that if parents do not want their child to participate in a huddle, have a huddle recorded that their child would be participating in, complete a post-huddle qualitative interview, to provide feedback about the huddle, or take surveys that they should contact the principal investigators of the study at the contact information listed on the sheet. Names of children who are not eligible to participate will be stored by the principal investigator in a password-protected file. The study team member responsible for data collection at a given team will be provided the list of children who are not eligible to participate, and these children, in addition to any children who do not provide assent, will not be eligible for the study. At games, if it's a huddle that will be recorded, the research assistant will announce beforehand that the huddle will be recorded, ensuring to capture the announcement on the recording. Subsequently, when stakeholders are approached in person at a game or practice they will be asked to provide an affirmative consent or assent to participate and be offered a written copy of the information sheet with study team contact information. Athlete participants will review an assent document and provide verbal assent (see Athlete Assent Sheets). For Aim 3, teams and stakeholders in leagues that are randomized into the control arm will receive an email explaining the study and what might be asked of them (i.e. asked to complete surveys) and that participation is voluntary. When athletes are called upon to complete surveys, they will receive assent sheets specific to the activity and will provide a verbal assent.

**Waiver of Written Documentation of Consent for all subjects**

We are requesting a waiver of documentation of consent. Given the large number of subjects who may be participating in the huddles, it would be extremely difficult to get verbal or written consent just to observe subjects in the huddles or record huddles where most participants will not be heard or identifiable. In addition, emails and information sheets will be sent to potential subjects prior to the huddles. The information sheets will inform subjects that participating in the huddles indicates their consent, and that subjects who do not want to participate may contact the study team to request not participating.

In addition, subjects who participate in the interviews and surveys will have oral consent/assent obtained prior to doing these portions. For those who will be doing their surveys online, the subjects will be provided the information sheet prior to completing the survey. In addition, the following reasons also describe why the waiver should apply:

- In the absence of a waiver, we would be limited in our ability to complete data in this population.
- The main risk is confidentiality, thus obtaining documentation of consent will actually increase risk to subjects.
- Subjects will be provided with an information sheet which will detail potential risks and benefits of participating and researchers will answer any questions they may have, when the surveys are administered in person. The research involves no procedures for which written consent is normally required outside of the research context.

**Waiver of Consent/Assent & Parental Permission for Observation in the Huddles, Complete Interviews, and complete surveys**

We are also requesting a waiver of consent, assent, and parental permission for subjects who may not be able to read the information sheet prior to being observed in the huddles. In addition, some child subjects may be approached for interviews and surveys without parental permission. The following reasons describe why the waivers are justified:

- We are asking stakeholders to complete surveys and interviews. Written information describing the research is to be provided to the subject or the subject's legally authorized representative.
- This research is minimal risk as it involves no drugs or devices. We are testing whether having athletes, coaches and parents organize into a huddle and reaffirm safety prior to a game can change the culture of sport, and thereby decrease concussion. In addition, questions asked during the interview or surveys do not involve sensitive information as
  the questions ask about demographics, the effectiveness of the huddles, team norms, and whether the child may have had a concussion.

- Information about the study will be distributed to the subjects and parents before any study activities take place, and information sheets/assent sheets will be provided if and when conducting interviews or completing surveys in person. However, it would be impracticable to obtain parental permission, consent and assent individually from study participants before each game, because the number of participants could potentially be very large, including entire teams, their coaches, parents, medical providers and referees. More than likely, one or only a few research assistants will be present each time. In addition, not all parents will be in attendance, as many parents send their children with other parents or in a carpool.

**Waiver of Parental Permission for Referees**

For those who are working as referees, but who are not yet 18, parental or guardian permission is not reasonably required to protect the subjects and, therefore, we request a waiver of parental permission:

- The research is not FDA-regulated.
- The research does not involve non-viable neonates.
- The research involves no more than Minimal Risk to the subjects.
    - Referee participants who are minors would only be included in activities such as the safety huddle, surveys, and interviews about the safety huddle.

- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
    - Participants will be given written information informing them that research is voluntary, how to opt-out of the study, and explaining their rights and what they will be asked to do as a participant.
- The research could not practicably be carried out without the waiver or alteration.
    - Referees who are not yet 18 years old, in some leagues, make up a large number of the referees, thereby making it important to include them in the intervention. Additionally, as this is their job, it is not reasonable to assume that
      their parents will be in attendance for the games nor accesses the correspondence between their child and their child's employer.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**HIPAA Waiver of Authorization**

- Only for Aim 3 will measures include questions about the patient's health history, such as concussion incidence (please see attached measures).
- For all aims, the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, because of the protections we have in place,
  per Sections 6, 12, and 26 of this document (i.e. an adequate plan to protect the identifiers from improper use and disclosure, to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, and written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512). For example, in order to decrease the risk to confidentiality, as noted in Section 12.1, athletes will write their name on the first page of the first survey (to be detached from the rest of the survey upon completion) and each participant will create their own unique study ID. The research could not practicably be conducted without the waiver or alteration, because parents are often not in attendance during games when survey measures will be piloted in aim 1a and administered in aim 3, making it impracticable to get parental signatures. Additionally, there will be many participants and only one study team member, making verbal authorization difficult to obtain for a potentially large number of parents and athletes.
- Parents and athletes will, however, receive the email and information sheet before the athlete is ever approached and are given the appropriate information to opt their child out of study participation, as well as what general topics (i.e. demographics, team norms, concussion history, etc) the surveys will include.
- The research could not practicably be conducted without access to and use of the protected health information, because in order to measure both intentions about engaging in these concussion risk behaviors and performed athlete behavior, we need to gather information from the athletes about previous concussions they've sustained, along with their demographic information.

**Waiver of Consent for Subjects who turn 18 during the Data Analysis Phase:**

For the small number of subjects who turn 18 during the data analysis phase, they will not be reconsented. Therefore, we request a waiver of consent:

- The research is not FDA-regulated.
- The research does not involve non-viable neonates.
- The research does not involve newborn dried blood spots.
- The research involves no more than Minimal Risk to the subjects.

- All procedures that study participants will be involved in are low-risk such as the safety huddle, surveys, or interviews about the safety huddle.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
  - Participants will have already assented to be a part of the study and have received written study information for all procedures.
- The research could not practicably be carried out without the waiver or alteration ○ We will not have identifiable information for these subjects, therefore we cannot reconsent them.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Subjects who are not yet adults (infants, children, teenagers)** For youth athletes to participate, they will be required to review an information sheet describing the study and if they are participating in the survey/interviews, provide verbal assent. Youth participants whose parents have declined participation by contacting the principal investigator will not be eligible to participate in the study.

We do not expect any subjects to turn 18 while actively participating in the study as the athletes that are followed longitudinally will be middle school aged at the time of study initiation. Additional athlete participants from 8 to 17 years old may participate in the study by piloting measures or participating in a huddle, but they would not be followed longitudinally. Some referees who are not yet 18 may participate in huddles, interviews, and/or surveys but they will not be followed longitudinally either.

All huddle participants will be notified in their pertinent stakeholder group's Information Sheet and Email about the huddles and how to opt out. These documents include language for minors as well as adults. For other study activities, verbal consent or assent will be asked for at the time of the activity.

**Cognitively Impaired Adults**

N/A

**Adults Unable to Consent**

N/A

**Consent for use of HUD**

N/A

**Cognitively Impaired Adults**

☐ N/A

**Adults Unable to Consent**

☐ N/A.

## 30.0 Process to Document Consent in Writing

We are requesting a waiver of written documentation of consent as the study involves no more than minimal risk (see Section 29).

## 31.0 Drugs or Devices

N/A

## 32.0 Good Clinical Practice

N/A

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