Developing a Tool to Support Shared Decision-Making Post-Concussion Between Adolescents, Parents and Clinicians

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Due to the smaller sample recruited we simplified our analytic plan to focus on between-condition comparisons for the primary decision-related outcomes and no subgroup comparisons.

PROJECT TITLE:

Family shared decision making: Piloting a decision aid for adolescent sport

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1. Objectives

1.1. Purpose, specific aims, or objectives:

The purpose of this study is to understand the perspectives of adolescents, parents, and clinicians on the decision to resume or cease sport participation following recovery from a sport-related concussion. Specifically, this study will test the effectiveness of created decision aids to help with this understanding and discussion. The specific aims of this study are four-fold:

Aim 1: Conduct surveys with clinicians (inclusive of pediatrician and family medicine providers) and families who have an adolescent recovering from a sport-related concussion (one parent and one adolescent) about their experiences discussing return to sport. Specifically, this aim will survey clinicians about their current knowledge and belief of concussion research, their experiences with discussing return to sport post-concussion with families, and their opinions for best practices and needs for creating an effective shared decision-making aid with families on this topic. This aim will also survey parent-adolescent dyads about their experiences making the decision to return to sport. Findings from this aim will directly influence Aims 3 and 4.

Aim 2: First, this aim will include semi-structured interviews (inclusive of cognitive interviewing, qualitative interviewing) with families (one parent and one adolescent) in order to learn more about their experiences making decisions to resume or stop sport participation after recovery from a sport-related concussion . Second, this aim will conduct usability testing with families (one parent and one adolescent) and their clinicians with created parent and adolescent decision aids for enabling return to sport discussions following a sport-related concussion. Specifically, this aim will involve usability tests (i.e., interview + tasks) to evaluate the effectiveness of current decision aids for parent and adolescent and provide feedback on ways to tailor the current decision aids better. Findings from this aim will be used directly in Aim 4.

Aim 3: First, this aim will include semi-structured interviews (inclusive of cognitive interviewing, qualitative interviewing) in order to receive directed and specific clinician feedback on how to create a decision aid effectively for their use.

Aim 3 (continued): Second, this aim will conduct usability testing with clinicians (including pediatricians and family medicine providers) for a clinician-specific decision aid. The findings from Aim 1 and Aim 2 will help inform the creation of a clinician-specific decision aid. Findings from this aim will be used directly in Aim 4.

Aim 4: This aim has two cohorts:

Aim 4a: Cohort 1 will evaluate how shared decision making currently occurs in a clinical appointment. This data will then be used to compare need and impact of the intervention group in Aim 4b.

Aim 4b: Cohort 2 includes a pilot random control trial (RCT) of all three decision aids (i.e., parent, adolescent, clinician) to assess intervention efficacy of all decision aids in aiding family shared decision making in returning to sport post-sport related concussion.

1.2. Hypotheses to be tested:

This research is qualitative; therefore, we do not have any hypotheses to explicitly test.

2. Background

2.1. Relevant prior experience and gaps in current knowledge:

Sport-related concussion is a prevalent injury among U.S. youth. More than 1 million youth sport participants are diagnosed each year,[1] with incidence highest in sports that involve routine contact and collision such as football, soccer and ice hockey.[17] Most state and sport organization policies require clearance by a medical provider before an athlete returns to organized sport post-concussion,[18] typically affirming that acute symptoms have resolved and no new symptoms present with a graded increase in physical activity.[18] For most youth this occurs within one-month post-injury.[19,20] The only absolute contraindication for returning to contact/collision sport is a structural brain abnormality visible on neuroimaging, which is rare and usually unrelated to the diagnosis of concussion.[21,22] As a result, returning to contact/collision sport complies with current standards of care for nearly all children with resolution of acute concussive symptoms.

Medical clearance, however, does not mean that return to sport is free from risk. Even when athletes have recovered from their acute injury symptoms, they may be at risk of later-life neurologic dysfunction. Indeed, there is emerging evidence that the burden of concussion may be cumulative,[23,24] though there is no definitive evidence about a dose-response relationship for concussions sustained in youth sport and later-life harm, with data largely from short-term studies[25] and retrospective cohort studies of professional athletes that may not generalize to youth populations.[26] Possible later life harm notwithstanding, returning to contact/collision sport means risking sustaining an additional concussion, which is often accompanied by short-term psychosocial consequences, including impaired academic and social functioning,[2] and there is evidence that individuals with prior concussions are at increased risk of future concussions.[5]

Many U.S. families are concerned about concussion[7] and seek counsel from clinicians about sport participation post-injury.[27] Yet clinicians struggle with how to discuss with families whether or not child patients should return to contact sport post-concussion. In part this is because the evidence supporting each option is not definitive. It is also due to the fact that this decision is highly individualized. Influential factors in this decision include clinical variability (e.g., injury severity, recovery trajectory, type of functional impairment post-injury, the interval between prior injuries, the age at which injuries occurred, and premorbid health conditions),[5,21] and different family tolerance for the uncertain risk of harm associated with sustaining an additional concussion relative to what they see as the benefits of returning to sport and the risks and benefits of substitute activities.[7–10] Given this context, a recent report by the Institute of Medicine[5] indicates a need for effective communication and dissemination strategies to facilitate decision-making post-concussion among athletes, parents and other stakeholders.

Shared decision-making is appropriate for return to sport decisions after concussions that do not result in medical disqualification. Not all options have to be equivalent in terms of their medical burden for shared decision making (SDM) to be appropriate, if all meet current standards of care.[28] There are two main situations in which our formative interviews with clinicians indicate SDM would be appropriate: (1) the clinician believes that medical harms of returning to contact/collision sport outweigh benefits, but the burden does not reach the threshold of mandatory medical disqualification ("retirement recommended"), and (2) the clinician believes there is medical equipoise between the costs and benefits of returning to contact/collision sport but the family is concerned ("no recommendation"). In the "retirement recommended" condition, the clinician would share a recommended course of action (e.g., ceasing contact/collision sport) and attempt to help the family—adolescent and parents—embrace the values and preferences that align with this recommendation.[28] In the "no recommendation" condition, SDM would

appropriately take a patient-led form, with the clinician in a facilitative role.[28] While decision-making post-concussion with minors will necessarily also involve parents, explicit efforts to elevate the voice of adolescents, particularly when there is medical equipoise in the decision, is developmentally appropriate[29] and supports growth in their efficacy in making healthcare related decisions.[30]

A decision aid can help facilitate higher quality shared decision-making post-concussion. High quality decisions are facilitated by a decisional process where: all parties involved recognize that a decision has to be made, feel informed about the risks and benefits of key options, and are clear on what matters most to them.[12,13] At present, these criteria are inconsistently met post-concussion. Many parents and adolescents are inadequately informed about the short- and long-term risks of concussion, with this deficit magnified among lower socioeconomic status families.[9,31,32] Discussions about possible contact/collision sport retirement tend to occur when the clinician believes cessation would be medically beneficial, often around 4 concussions or after concussions with prolonged symptoms.[9,33] However, we have found that most parents of youth football players would prefer this conversation to be initiated earlier after 1 or 2 concussions (Kroshus et al., under review). We have also found that timing of this conversation is influenced by the clinician's subjective assessment of the athlete's on field and academic potential.[33] Use of a decision aid post-concussion could help clinicians have a better balanced discussion on the timing and nature of post-concussion communication about sport retirement, ensuring that all families are informed about relevant risks and benefits of different sport options.

2.2. Relevant preliminary data:[1]
See section 2.1

2.3. Scientific or scholarly background:
See section 2.1

2.4. Prior approvals:
N/A

3. Study Endpoints[2]

3.1. Primary and secondary endpoints:

Aim 1: Recruitment of participants will occur until thematic saturation, or until 500 participants are reached (100 clinicians, 200 parents, 200 adolescents). For each participant, the endpoint will be the conclusion of the survey.

Aim 2: Recruitment of participants will occur until thematic saturation. For each participant, the endpoint will be the conclusion of the interview and/or usability testing.

Aim 3: Recruitment of participants will occur until thematic saturation. For each participant, the endpoint will be the conclusion of the usability testing.

Aim 4a and 4b: Recruitment will continue until 40 families agree to participate (20 per phase) and up to 20 healthcare providers (Aim 4b only). For each family, participation will conclude after completing the 3-month follow-up survey. For each healthcare provider, participation will conclude after completing the brief survey about tool implementation.

3.2. Primary or secondary safety endpoints:
There are no primary or secondary safety endpoints for this study.

4. Drugs, Devices and Biologics[3]

4.1. Manufacturer and name of all drugs, devices and biologics:
N/A

4.2. Description and purpose of all drugs, devices and biologics:
N/A

4.3. Regulatory status of all drugs, devices and biologics:[4]
N/A

4.3.1. Drugs or Biologics:
☐ IND Exempt. Explain:[5] ✍Click here to enter text.
☐ IND.

4.3.2. Devices:
☐ IDE Exempt. Explain:[6] ✍Click here to enter text.
☐ Abbreviated IDE / Non-Significant Risk. Explain:[7] ✍Click here to enter text.
☐ IDE / Significant Risk.

4.4. Plans to store, handle, and administer any study drugs, devices and biologics so they will be used only on subjects and be used only by authorized investigators:
N/A

5. Procedures Involved

5.1. Study design:[8]
This study involves the following procedures:

Aim 1: Survey

Aim 2: Interviewing (i.e. qualitative) and Usability Testing

Aim 3: Interviewing (i.e., cognitive, qualitative) and Usability Testing

Aim 4a and 4b: Consecutive cohort design (families). Healthcare providers will also complete a one-time survey.

5.2. Research procedures:[9]
Aim 1: **Clinicians**: This aim will survey clinicians about their current knowledge and belief of concussion research, their experiences with discussing return to sport post-concussion with families, and their opinions for best practices and needs for an effective shared decision-making aid with families on this topic. Participants will receive a link to an online survey, hosted on a survey-hosted site (e.g., REDCap). Before beginning the survey, participants will read an information sheet about the study and then proceed to the survey, which will ask them questions relating to the topics described above. After completing the survey, participants will be exited from the survey and data collection will end for this aim. Survey questions can be found in the attachment section on Click.

Parents and adolescents: This aim will also survey families (one parent and one adolescent) about their experiences with discussing return to sport post-concussion and with deciding what sports and activities to participate in post-concussion. Parent participants will be contacted first and will receive a link to an online survey, hosted on a survey-hosted site (e.g., REDCap). Before beginning the survey, parents will read an information sheet about the study, indicate their agreement to participate and permission for their adolescent to participate, and then proceed to the survey, which will ask them questions relating to the topics described above. Adolescent participants will follow a similar process and indicate their assent to participate before continuing on to the survey. After completing the survey, participants will be exited from the survey and data collection will end for this aim. Survey questions can be found in the attachment section on Click. Surveys will be completed separately by parents and adolescents.

Aim 2: This aim involves semi-structured interviews, and usability testing sessions(i.e., usability test interview + tasks) with families (parent and adolescent). as described below. Once a participant is enrolled in this aim, participants will participate in either a 60-minute interview (in-person or online), and/or an in-person or online usability testing session. For semi-structured interviews, participants (i.e., parents and adolescents) will review an information sheet about the study prior to the interview. Then, they will be interviewed separately about their experiences making decisions to resume or stop sport participation after recovery from a sport-related concussion. All interview data will be audio recorded. All interviews conducted online will be done so through an online platform (i.e., Zoom) and their online session recorded. For in-person usability sessions, first, participants (i.e., parent-adolescent dyad) will be given a brief demographic questionnaire at the start of the usability testing session. Then, each parent-adolescent dyad will take their respective decision-making tool. After taking the tool, they will be asked questions related to the tool usability. The entire usability testing session will be audio recorded. Participants will be given an information sheet about the study at the start (i.e., before demographic questionnaire) of the usability testing session. For online usability testing sessions, the same procedures will be followed as in person usability sessions, however, participants will be emailed the demographic questionnaire and information sheet and they will participate in the usability session via an online platform (i.e., Zoom). Their online session will be recorded. All documents used in this aim can be found in the attachment section on Click.

Aim 3: This aim involves semi-structured interviews, and usability testing with clinicians as described below. Usability testing will be informed by the interviews and will be submitted for IRB review after the interviews are complete. Participants (i.e., clinicians) will participate in a 60-minute interview, either in person or online. Prior to the start of the interview, participants will review an information sheet about the study that will either be emailed to them (if session is conducted online) or printed and handed in person (if session is conducted in person). Then, they will be interviewed (inclusive of cognitive interviewing, qualitative interviewing,) about specific clinician feedback on how to create a decision aid effectively for their use. All interview data will be audio recorded. All documents used in this aim can be found in the attachment section of Click. All interviews conducted online will be done so through an online platform (i.e., Zoom) and their online session will be recorded.

Aim 4a and b: In the first data collection cohort (Aim 4a), there will be no change to the nature of provider communication with families seeking care for their child's concussion. In the second cohort (Aim 4b), the study team will share the respective decision aids with the family and let them know to complete them before their appointment. After both the parent and adolescent complete their respective decision aids, a member of the study team will insert the clinician tool link in the patient's chart and/or send a message with the link for the clinician to review, prior to the appointment.

Data will be collected about the experience that families have discussing the decision of what sports and activities they participate in after they recover from their injury and using their respective decision aids (intervention only). Survey data will be collected from parents and adolescents at several time points (baseline, post-visit(s)up to and including their final visit, 3-months after initial visit). Survey data will also be collected from healthcare providers about their experiences sharing information with families and using the tool (intervention only) over this time period. Data will be collected at one time point (after a patient of the healthcare provider has completed the tool).

5.3. Data sources that will be used to collect data about subjects:[10]

Interviews (inclusive of cognitive, and qualitative), surveys, usability testing. All data will be derived from participants.

5.4. Data to be collected, including long–term follow–up data:[11]

Aim 1: Data will be derived from participants (i.e., clinicians – inclusive of pediatricians and family medicine providers, parents, adolescents). Data will come from online surveys. All the data to be collected is outlined in the enclosed data collection forms and may contain identifiable information- such as employment title (clinicians) or number of concussions (adolescents).

Aim 2: Data will be derived from participants (i.e., parents, adolescents) who participate in either an in person or online interview and/or usability testing session. The source records that will be used to collect data from participants (e.g., interview guide, demographic questionnaire, usability testing guide, including post task semi-structured interviews) are attached to the Click Smartform. Data may contain identifiable information – such as number of concussions and/or zip code. The semi-structured interviews and/or usability testing sessions may change iteratively based on feedback from participants, but themes explored will remain the same, consistent with best practices qualitative data collection.

Aim 3: Data will be derived from participants (i.e., clinicians – inclusive of pediatricians and family medicine providers) who participate in either in person or online interviews. Data may contain identifiable information- such as employment title. The source records that will be used to collect data from participants (e.g., demographic questionnaire,, including post task semi-structured interviews and one-on-one interviews) are attached to the Click Smartform. Data may contain identifiable information – such as number of concussions and/or zip code.

Aims 4a and 4b: Survey data will be collected from up to 40 families (parent + child) (20 per phase) at a minimum of 3 time points: their first visit, after each following visit up to and including their final visit, and 3-month follow-up (i.e., 3 months after their initial visit). Data will come from online surveys, completed online or in-person while at their visit (e.g., participants will be given a tablet to complete while waiting). If participants are not able to complete the relevant surveys in-person at their visit, they will complete the follow up survey by telephone (call or text linking to a survey hosted on REDCap), or by email (linking to a survey hosted on REDCap). Survey data will also be collected from up to 20 healthcare providers at one time point (towards the end of family data collection) about their experiences using the tool.

For participants enrolled in the intervention group (4b only), online data will also be collected within their respective decision aids. See the online versions of "Parent Tool", "Adolescent Tool", and "Family Discussion Tool" attached to the Click SmartForm, to see the data that will be collected within the decision aids.

6. Data and Biospecimen Banking[12]

6.1. Complete list of the data and/or biospecimens to be included in the bank:[13]

N/A

6.2. Location of data and/or biospecimen storage:[14]

N/A

6.3. List of those with direct access to data and/or biospecimens in the bank:

N/A

6.4. Length of time data and/or biospecimens will be stored in the bank:

N/A

6.5. Procedures for protecting the confidentiality and privacy of the subjects from whom the data and/or biospecimens were collected:[15]

N/A

6.6. How the data and/or biospecimens will be made available for future use:

N/A

6.6.1. Who can request data and/or biospecimens from the bank:

N/A

6.6.2. Format in which data and/or biospecimens will be provided:

N/A

6.6.3. Process for investigators to request data and/or biospecimens:[16]

N/A

6.6.4. Restrictions on future use:[17]

N/A

6.6.5. Plan for providing data results from banked data/biospecimens:

N/A

7. Sharing of Results

7.1. Plan to share results with subjects/others:[18]

Aggregate data will be shared with members of the research team and disseminated via peer reviewed publication. No personal identifiers will be shared.

A subset of information from the individual parent and adolescent tools will be synthesized and presented in the family discussion tool to guide the conversation (see the online version of the "Family Discussion Tool" attached to the Click SmartForm). The link to the clinician tool will be inserted into the patient's chart and/or sent to the clinician via a clinician coordination message for the clinician to review prior to their appointment. There is no other plan to share results with the research subjects.

8. Study Timelines

8.1. Duration of an individual subject's participation in the study:

Aim 1: For each participant, the end point will be the conclusion of the survey.

Aim 2: For each participant, the end point will be the conclusion of the semi-structured interview and/or usability session (including interviewing).

Aim 3: For each participant, the end point will be the conclusion of the interview.

Aim 4a and Aim 4b: For each parent-adolescent dyad participant, the end point will be the conclusion of the 3-month follow-up survey. For healthcare providers (Aim 4b), the end point will be the conclusion of the survey.

8.2. Duration anticipated to enroll all study subjects:

Aim 1: 3 months (up to 5 months)

Aim 2: 3 months (up to 5 months)

Aim 3: 3 months (up to 5 months)

Aim 4a: 6 months (potentially up to 12 months)
Aim 4b: 6 months (potentially up to 12 months)

8.3. Estimated date for the investigators to complete this study:

Primary analyses will be completed about 2 years after the start of the study.

9. Study Population[19]

9.1. Inclusion criteria for each subject population (e.g., patients, parents, providers):

Aim 1: Inclusion criteria *for parents, adolescents, and clinicians* (inclusive of pediatricians and family medicine providers):

1) Is an adolescent:
    a. Between the ages of 11-17 years (inclusive)
    b. Has sustained one concussion during the past 5 years
2) Is a parent of an adolescent who meets inclusion criteria in point 1
3) Is a clinician who has treated any of the above listed participant characteristics (point 1)

Aim 2: Inclusion criteria *for parents, adolescents, and clinicians* (inclusive of pediatricians and family medicine providers):

1) Is an adolescent:
    a. Between the ages of 11-17 years (inclusive)
    b. Has sustained at least one concussions during the past 3 years
2) Is a parent of an adolescent who meets inclusion criteria in point 1

3) Is a clinician who has treated any of the above listed participant characteristics (point 1).

Aim 3: Inclusion criteria *for clinicians* (inclusive of pediatricians and family medicine providers):

1) Treats adolescents between 11-17 years of age
2) Has treated an adolescent who:
    a. Is between the ages off 11-17 years (inclusive)
    b. Has sustained a concussion during the past 3 years

Aims 4a and 4b: Inclusion criteria *for parents, adolescents, and clinicians* (inclusive of pediatricians and family medicine providers):

1) Is an adolescent:
    a. Between the ages of 11-17 (inclusive)
    b. Has sustained a concussion during the study period
2) Is a parent of an adolescent who meetings inclusion criteria in point 1
3) Is a clinician who has treated any of the above listed participant characteristics (point 1) and that family has enrolled in Aim 4b.

9.2. Exclusion criteria for each subject population:

There are no exclusion criteria outside of those that do not meet the above listed inclusion criteria.

9.3. Populations with special considerations, involved in the study:[20]

☒ Children/Teenagers[21]

Risk assessment specific to this vulnerable population and additional safeguards:[22]

Private and potentially identifiable data will be collected about adolescents. Even with this risk, the study still has minimal risk to adolescents. Additionally, adolescents will be able to contact a research study team member at any time to ask questions or stop participation. They will be reminded that all participation is voluntary, and they will be asked to assent to study participation.

☐ Children who are Wards of the State[23]

Risk assessment specific to this vulnerable population and additional safeguards:

N/A

☐ Adults Unable to Consent [24]

Risk assessment specific to this vulnerable population and additional safeguards:

N/A

☐ Neonates of Uncertain Viability or Non–Viable Neonates[25]

Risk assessment specific to this vulnerable population and additional safeguards:

N/A

☐ Pregnant Women[26]

Additional safeguards:

N/A

☐ Prisoners[27]

Additional safeguards:

N/A

☐ Economically or educationally disadvantaged persons[28]
Additional safeguards:
N/A

10. Number of Subjects

10.1. Total number of subjects to be enrolled locally:[29]

Aim 1: We anticipate recruiting about 100 clinicians (inclusive of pediatricians and family medicine providers) and 200 parent-adolescent dyads.

Aim 2: We anticipate recruiting about 20 dyads (parent-adolescent) for semi-structured interviews and 20 dyads (parent-adolescent) or triads (parent-adolescent-clinician) for usability testing.

Aim 3: We anticipate recruiting about 20 clinicians (inclusive of pediatricians and family medicine providers).

Aims 4a and 4b: We anticipate recruiting about 40 dyads (parent-adolescent) (i.e. 20 per phase) and 20 healthcare providers (Aim 4b only).

10.2. Total number of subjects to be enrolled across all participating sites:[30]
N/A

10.3. Number of screened subjects versus the actual number enrolled in the research:[31]

Aim 1: We estimate that we will need to screen 400 clinicians to enroll 200 eligible participants and 400 parent-adolescent dyads to enroll 200 eligible participant dyads.

Aim 2: We estimate that we will need to screen 80 dyads and/or triads in order to enroll 40 dyad and/or triad participants.

Aim 3: We estimate that we will need to screen 40 clinicians to enroll 20 participants.

Aims 4a and 4b: We estimate that we will need to screen 100 dyads or triads to enroll 40 eligible participant dyads or triads (20 dyads or triads per phase). We estimate that we will need to screen 25 healthcare providers to enroll up to 20 (Aim 4b only).

10.4. Power analysis:

Aim 1: This data is primarily being assessed for qualitative responses; therefore, no power analyses are being assessed.

Aims 2 & 3: This data is primarily qualitative, and thus a power calculation is not appropriate.

Aim 4a and b: We anticipate enrolling 20 families per study phase; allowing for 15% attrition an estimated 17 per phase would complete the study. Conservatively estimating 15 families per phase, we will have ≥80% power to detect a difference in decisional regret (range: 0 to 100 points) as small as 7.1, 3.0 and 1.2 points, for SD = 12, 5, and 2, respectively. These estimates assume an alpha of 0.05 and SD ranging from 1-12. The data from the healthcare provider survey is primarily qualitative, and thus a power calculation is not appropriate.

11. Withdrawal of Subjects

11.1. Anticipated circumstances under which subjects will be withdrawn from the research without their consent:

We do not anticipate circumstances under which participants will be withdrawn from the research without their consent.

11.2. Procedures for orderly termination:

N/A

11.3. Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and withdrawal from data/biospecimen banking:

Participants may withdraw from the study at any time by notifying study personnel. Once a participant expresses their desire to withdraw, the researcher will terminate data collection. The study team will review, on a case-by-case basis, whether partial data collected will be used in the analysis.

12. Risks to Subjects

12.1. Reasonably foreseeable risks to subjects (include each study population, each arm, and optional procedures):

This study involves no more than minimal risk to participants. Potential risks include the risk of loss of confidentiality and the following:

Aim 1: Testing burden – participants may experience inconvenience associated with answering survey questions.
Aims 2 & 3: Loss of confidentiality – participants may provide identifiable information about themselves, and in the case of parents, their adolescent.
Aims 4a and 4b: Testing burden- participants may experience inconvenience associated with answering survey questions; Loss of confidentiality—participants may provide identifiable information about themselves, and in the case of parents, their adolescent

12.2. Procedures with unforeseeable risks:

N/A – there are no procedures that pose unforeseeable risks.

12.3. Procedures with risks to an embryo or fetus should the subject be or become pregnant:

N/A

12.4. Risks to others who are not subjects:

N/A

12.5. Procedures performed to lessen the probability or magnitude of risks:

All data will be kept in secure and locked locations. Additionally, all participants will be given the option of speaking to a research study team member at any time, to ask questions or express concerns over research participation. See section 15.1 for additional details on steps that will be taken to mitigate risks to confidentiality.

13. Potential Benefits to Subjects

13.1. Potential benefits that individual subjects may experience from taking part in the research:[32]

There is no anticipated benefit of participating in this study.

14. Data Analysis/Management

14.1. Data analysis plan, including statistical procedures:

Aim 1: Survey responses will be reviewed with a focus on the psychometric properties of items and scales (e.g., how are items distributed), as well as evaluate what answers are correlated. We will compare responses across key characteristics (e.g., clinician characteristics, beliefs) to determine what key beliefs and feedback are across all clinicians, parents, and adolescents.

Aim 2 & 3: Thematic analysis will be used to systematically code transcripts and identify emergent themes. Qualitative data will be digitally recorded and transcribed verbatim and coded for relevant themes using a thematic analysis approach. Coded segments may be entered into a qualitative coding software (e.g., Dedoose) to facility analysis or will be analyzed by quantified elements. Data will continue to be conducted until emergent results iteratively inform and clarify the final version of the decision aids.

Aim 4a and b: We will compare socio-demographic (e.g. age, sex, health literacy) and clinical characteristics (e.g. concussion history and severity at baseline) between the control and intervention groups. Differences in primary decision process and quality outcomes will be compared between treatment and control conditions using Structural Equation Modeling, where parent and child measures will be examined in parallel. Family level non-independence will be modeled by residual covariances between parent(s) and child measures. Outcomes will be pooled across the retirement recommended and equipoise conditions as decision process and quality measures are equally relevant in both conditions. Secondary analyses related to health behaviors (contact sport participation and physical activity) and health status outcomes at Time 3 will be compared between treatment and control conditions using logistic regression. **Dyadic and triadic analyses.** Dyadic/triadic concordance will first be described using contingency tables. Next, actor-partner interdependence models will be used to assess the effects of each family member's decision process measures on their own decision quality measures and the rest of the family's decision quality measures ("partner" effects). Healthcare provider survey responses will be reviewed and compared to determine key beliefs and feedback across all healthcare providers.

14.2. Quality control procedures for collected data:[33]

The Principal Investigator and study Research Scientist will train any research assistant(s) and additional study team members on best practices for qualitative and quantitative data collection through workshops, practice interviews, and/or individual supervision. As an additional quality check, interviews will be audio-recorded and reviewed regularly to ensure high-quality data collection methods are used.

15. Confidentiality and Privacy[34]

15.1. Procedures to secure the data and/or biospecimens during storage, use, and transmission:

During data collection, all research materials containing personally identifiable information will be kept in a locked container or on a secure password protected server while not in use.

Any data collected via survey will be collected by an online secured survey hosting site (e.g., REDCap). Survey data will only be accessible to members of the study team. All survey data will be password protected and the study PI and Research Scientist will be gatekeepers of access.

Information collected and/or presented via the decision aids (parent, adolescent, clinician) will be housed on it's own website (valuedaction.com).). All traffic to and from the Valued Action site is encrypted via SSL. All users of Valued Action have access only to their own or relevant data (as defined by the project requirements). Healthcare professionals can only access summary data relating to their patients. Direct database access is restricted to a local subnet, accessible only with a private key. All data is stored encrypted at rest. Every effort has been made to minimize the data stored, to only include data points specifically required to achieve the project goals.

As noted, any data that is collected via recording will be kept on password protected devices (i.e., the audio recordings will be on a password protected device). All interviews conducted in person will be recorded via a normal recording device not connected to the internet (either password protected or secured in a locked cabinet if not password protected) and all interviews conducted online will be recorded via the online platform (i.e. Zoom) and all data will be secured on Seattle Children's servers. Transcribed audio-recorded interviews will be de-identified and stored on the secure Seattle Children's servers, accessible only to the study team; a numeric code will be used to link audio interviews to participants.. Only coded segments (without identifiers) of recordings may be entered into a qualitative data software (e.g., Dedoose). The link between study code and participant information will be kept in a password-protected file, separate from the research data, and overseen by the Principal Investigator and study team Research Scientist. Data will not be transported outside of Seattle Children's, unless data is being transmitted to contracted transcriptionists to transcribe audio data.

When conducting study procedures online (i.e., interviews, usability testing), we will be using the latest version of Zoom, make the meetings private, require passwords for meeting entry, disabling private chat, and consent will be obtained prior to recording. We will utilize the screen sharing function to share instruments (e.g., decision aids) with participants for feedback in interviews, usability testing sessions, etc. The original versions of the decision aids (that will be iteratively adapted throughout testing) to be shared have been uploaded to the Click platform.

After data is collected, any information which would identify the participant(s) will be removed and code numbers used instead. All identifiers will be destroyed within 6 months of completion of data collection.

All recorded data will be recorded on one of the following: 1) virtually through Zoom (Aims 1-3 if participant chooses to conduct participation online); 2) normal recording device that is not connected to the internet (Aims 1-3 if conducted in person).

15.2. Steps that will be taken to protect the privacy interests of subjects:[35]

All data will be stored on password protected REDCap projects accessible only to members of the study team, secure Seattle Children's servers and/or in locked containers at Seattle Children's Research Institute. Participant identifiers will be kept in these secure storage options as well. Additionally, all interviews will take place either online, or at a location preferred by the participant for privacy or at a private location at a Seattle Children's Hospital and/or affiliated clinic. If participating at a Seattle Children's clinic, all participants will already

be affiliated with that clinic, as they will be attending it for an appointment. Private locations that are preferred by the participant will encourage comfortability, as well as privacy.

15.3. Location where the data and/or biospecimens will be stored:

Data will be stored on secure password protected REDCap projects, Seattle Children's servers and/or in locked containers at Seattle Children's Research Institute.

15.4. Length of time data and/or biospecimens will be stored:

Data will be stored for 5 years.

15.5. Individuals with access to data and/or biospecimens:

Data will only be accessible to the study team members, as specified by the PI or study Research Scientist.

15.6. Process for the transmission of data and/or biospecimens outside Seattle Children's:

15.6.1. List of data and/or biospecimens that will be transmitted:

Electronic data may be transmitted, and if so, it will only be transmitted if all data has been de-identified.

15.6.2. Individual(s) who will transmit data:

If any identifiable data is to be transported, it will be stored in a locked container until it returns to Seattle Children's Research Institute. Study team members will make every attempt to remove any identifiable information before transporting data. Study team members may transmit de-identified data electronically.

16. Provisions to Monitor Data to Ensure the Safety of Subjects[36]

16.1. Plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe:[37]

The study PI will check the data periodically in order to ensure that data is being collected according to approved guidelines, as well as perform data checks to ensure proper procedure protocols are being followed for all study team interactions with participants.

16.2. Data reviewed to ensure safety of subjects:

N/A

16.3. Safety information collection procedures:

N/A

16.4. Frequency of cumulative data review:

N/A

16.5. Conditions that trigger an immediate suspension of the research:

N/A

17. Use of Social Media

17.1. Types of social media to be used and how:

We will provide a brief summary of the study and a link to a contact form (housed on REDCap) for potential participants to fill out to community and sport organizations to send to their members through regular distribution channels (such as email listservs, social media pages

such as Facebook and/or newsletters). We will also post widely on other websites, such as www.craigslist.org and community forums/Facebook groups such as the West Seattle Blog and others.

17.2. Measures in place to protect the privacy or confidentiality of subjects:[38]

Social media will only be used for advertising recruitment materials approved for the study. We will only communicate basic study information with potential participants (i.e. what's in the relevant aim's information sheet) and let them know they must contact the study team to enroll.

17.3. Types of communications that will be submitted to the IRB for review:[39]

All advertisements on social media will use recruitment materials that have been approved by the IRB.

17.4. If user-generated content will be active, how it will be monitored and what actions will be taken to ensure subject safety and study integrity:

Comment functions will be enabled. If any questions are asked, we will provide responses in line with what is included in the relevant aim's information sheet and encourage the individual to reach out to the study team. After recruitment, we will update the post that recruitment is complete and disable the comment function.

18. Research Related Injury[40]

18.1. Available compensation in the event of research related injury:

N/A – there are no expected events of research that would relate or result in injury.

19. Recruitment Methods[41]

19.1. When, where, and how potential subjects will be recruited:

Aim 1:

Clinicians:

When: We plan to begin recruitment as soon as the study is approved

Where: We plan to recruit clinicians who work in pediatric sports medicine and have experience treating youth with concussions

How: We hope to recruit clinicians (inclusive of pediatricians and family medicine providers) through convenience and/or snowball sampling, and chart screening. We will begin recruiting clinicians from our own colleague referrals. After, we may utilize emails or web posting to additionally reach out to clinicians. We may send up to two recruitment emails per subject.

Parents and adolescents:

When: We plan to begin recruitment as soon as the study is approved

Where: We plan to recruit participants from chart screening, self-referral, and/or clinician referral who have attended Seattle Children's Hospital and/or an affiliated clinic during the last five years to be seen after sustaining at least one concussion.

How: We plan on asking Seattle Children's clinicians, an approved Seattle Children's medical professional (with approval), or an approved Seattle Children's entity (i.e. Clinical Data Analytics) to review patient charts on our behalf (note: we will not be reviewing patient charts ourselves, rather, through a clinician or other staff) to suggest participants for our study. Potential parent participants will first be provided with a written (mailed) letter than contains a QR code or a link for a survey (attached to the Click Smartform), and then subsequently

contacted via telephone (call or text message). Once parents agree to participate and give parental permission, adolescents will be sent the survey via text or email.

Aim 2:
When: We plan to begin recruitment as soon as the study begins, possibly collecting data concurrently with Aim 1.
Where: We plan to recruit participants from chart screening, self-referral, and/or clinician referral who have sustained a lease one concussion during the last three years.
How:
We hope to recruit parents, adolescents, and possibly their clinicians (inclusive of pediatricians and family medicine providers) through self-referral, convenience and/or snowball sampling. We plan on asking Seattle Children's clinicians, an approved Seattle Children's medical professional (with approval), or an approved Seattle Children's entity (i.e. Clinical Data Analytics) to review patient charts on our behalf (note: we will not be reviewing patient charts ourselves, rather, through a clinician or other staff) to suggest participants for our study. When we contact potential participants, we will ask the following questions to confirm they meet inclusion criteria: (1) child's age, (2) number of concussions, and (3) if child made a decision about return to sport as a result of their most recent concussion. We also hope to recruit participants from eligible survey participants in Aim 1 or Aim 4 who indicate they would be interested in participating in a qualitative interview about their experiences and/or usability testing session (after they have completed their time in their respective aim). We also will utilize contacts with coaches and community organizations (e.g., King County Play Equity Coalition, Greater Seattle Soccer League) to advertise and/or distribute our recruitment flyer in order to recruit individuals who sustained concussions and sought care outside of Seattle Children's. This flyer will include ways to get in contact with the study team, including a link to a contact form interested individuals can fill out in order to get in touch with the study team (please see "Aim 2 Recruitment Flyer" and "Aim 2 Contact Form" for details). We may also post a brief summary of the study and a link to the contact form on social media platforms (see section 17 above). We may also utilize snowball sampling and ask participants if they would be willing to forward the recruitment email to anyone they know who they think would be interested (see "Aim 2 Usability Testing Guide" for how we will phrase the question). We will begin recruiting clinicians from our own colleague referrals. These clinicians can help identify clinicians for us to reach out to who work with our desired population. After, we may utilize emails or web posting to additionally reach out to participants, including flyers and parent recruitment emails. We may send up to two recruitment emails per subject. For parent participants without email addresses available, we will first provide them with a written (mailed) letter and subsequently contact them via telephone (call or text message).

Aim 3:
When: We plan to begin recruitment after the completion of Aim 1.
Where: We plan to recruit clinicians who work in pediatric sports medicine and have experience treating youth with concussions
How: We hope to recruit clinicians (inclusive of pediatricians and family medicine providers) through convenience and/or snowball sampling, and chart screening. We plan on asking clinicians or approved Seattle Children's medical professionals (with approval) to review patient charts on our behalf (note: we will not be reviewing patient charts ourselves, rather, through a clinician or their staff) to suggest clinicians who treat our desired patient participant population for our study. We will begin recruiting clinicians from our own colleague referrals.

After, we may utilize emails or web posting to additionally reach out to clinicians. We may send up to two recruitment emails per subject.

Aim 4a:
When: We plan to begin recruitment as soon as the study begins
Where: We plan to recruit participants from Seattle Children's Sport Medicine
How: We hope to recruit families through chart screening. The study team will review the providers' schedules and identify patients who are being seen for sports-related concussions. Eligible families will be contacted by text or email, inviting them to participate. If interested, parents will be prompted to review a REDCap link with study documentation and fill out a contact form. Parents will have the option to speak with a member of the research team before agreeing to participate.. We may send up to three recruitment texts or emails per subject. Whenever possible, we will first contact eligible parents via email because we can get in contact with parents instantly, which is important when upcoming appointments may be within the same week. However, our partners in sports medicine have told us that parent emails are not always in the patient's chart. In the case email is not available, we will contact parents via text as that is another form of contact to get in touch with parents instantly and will ensure equal opportunities for all eligible families to participate.

Aim 4b:

When: We plan to begin recruitment as soon as the study intervention (i.e. the decision aids) is developed based on feedback in Aims 2 and 3
Where: We plan to recruit participants from Seattle Children's Sport Medicine
How: We hope to recruit families through chart screening. We will follow the same process outlined above in Aim 4a. A purposive subset of healthcare providers who are exposed to the tool (i.e., their patient was enrolled in the study) will be invited via email to complete a brief survey.

19.2. Steps that will be taken to protect potential subjects' privacy during the recruitment process:[42]
For all aims: Prior to accessing the survey, participants will receive information about the purpose of the study and eligibility criteria for the study. They will be informed that all participation is voluntary and confidential (depending on aim). Recruitment will always occur in a private location (i.e., participants will receive information online and can look at it when they prefer or will be spoken to in private locations when they prefer).

19.3. Sources of subjects:[43]
Seattle Children's Hospital, Seattle Children's Research Institute, Seattle Children's affiliated clinic, Seattle community organizations (parents and adolescents only) and/or other nationally recognized sports medicine programs (clinicians only). See section 19.1 for additional details by Aim.

19.4. Methods that will be used to identify potential subjects:
Snowball sampling, Convenience Sampling, Self-referral, Clinician referral, and/or Chart Screening.

19.5. Materials that will be used to recruit subjects:[44]

Possible recruitment materials include: 1) Recruitment Email to Parents; 2) Recruitment Email to Clinicians; 3) Flyer; 4) Web post, 5) Recruitment Letter to parents, 6) Recruitment Phone Call or Text Message to parents

19.6. Recruitment methods not controlled by Seattle Children's:
N/A

20. Consent/Assent Process

Consent/assent process overview:[45]

Aims 1-3: Consent materials (and the assent form when applicable) will be attached to recruitment emails and/or sent with recruitment letters. Additionally, after initial contact for recruitment is made, a link to REDCap, which will include the consent and assent materials appropriate to the given populations and aims, is emailed to participants prior to when their interviews/usability testing sessions occur. This strategy ensures that consent and assent forms will be presented to potential participants before they complete any study procedures.

In-person participants will be emailed consent materials (and the assent form when applicable) as an attachment to recruitment emails. Additionally, after initial contact for recruitment is made, a link to REDcap, which will include the consent and assent materials appropriate to the given populations and aims, is emailed to participants prior to when their usability testing sessions occur. When we meet in-person with the participant before their usability testing session, they will additionally be given a hard copy of the consent (and assent when applicable) forms.

Aim 4: Consent/assent materials will be included in the REDCap link that will be attached to recruitment emails/texts and/or sent to parents via mail or email prior to consent. Additionally, consent and assent materials appropriate to the given populations will be included at the beginning of the first REDCap survey sent to participants, which will ensure that consent and assent forms will be presented to potential participants before they complete any study procedures. Similar procedures will be followed for healthcare providers (i.e., the information sheet will be attached to recruitment emails and will be included at the beginning of the REDCap survey).

20.1. Where the consent/assent process will take place:

Aim 1: Consent will take place online, prior to the start of participation. See section above for details..

Aims 2 & 3: Consent will take place either in person or online prior to the start of the interviews and/or usability testing sessions by reviewing an information sheet or assent form. See section above for details. All interviews and usability testing consenting will take place online (if conducted online) or at a private location preferred by the participant (if conducted in person). Before any research procedures begin (online or in person), the team member conducting the interview and/or usability session will explain that the participant may choose to skip any questions they do not want to answer, and they may discontinue the research study at any time. Every study team member will take steps to make the interview and usability session feel like a conversation, based on supervision and training from the Principal Investigator and Research Scientist.

Aim 4a and 4b: All participants will review an information sheet online and have the option to consent/assent online or verbally during a phone call with a study team member, prior to the

start of any study procedures. If the participant wants to speak with a study team member, the study team will emphasize during the call that the participants may choose to skip any questions they do not want to answer, and they may discontinue the research study at any time. Participants will be provided with an opportunity to read through all documentation and to ask questions of the research team member involved in consent.

20.2. Steps that will be taken to protect prospective subjects' privacy during the consent/assent process:[46]

Aim 1: Participant survey data should remain confidential during the consent process. All consenting/assenting will take place online.

Aims 2 & 3: All interviews and usability testing consenting will take place either online or at a private location preferred by the participant.

Aim4a: All consenting will take place over the phone or online. If the participant wishes to speak to a study team member, the participant will be informed of the call beforehand so they can speak in a private location of their choosing.

20.3. Waiting period available between approaching a prospective subject and obtaining consent/assent:

All Aims: There is no waiting period between consent/assent and research procedures; consent/assent will be obtained immediately prior to conducting research procedures.

20.4. Process to ensure ongoing consent/assent:

N/A

20.5. If this box is checked, "SOP: Informed Consent Process for Research (HRP-090)" will be followed: ☒

20.6. If "SOP: Informed Consent Process for Research (HRP-090)" will not be followed, address the following:[47]

20.6.1. Role of the individuals listed in the application as being involved in the consent process:

N/A

20.6.2. Time that will be devoted to the consent discussion:

N/A

20.6.3. Steps that will be taken to minimize the possibility of coercion or undue influence:

N/A

20.6.4. Steps that will be taken to ensure the subject's understanding:

N/A

20.7. Non-English Speaking Subjects[48]

20.7.1. Anticipated preferred language(s) for subjects or their representatives:

Spanish

20.7.2. Presentation of Research Information and Documentation:

☒ Appendix A-10 of the Investigator Manual will be followed[49]

☐ Short form procedures may be used per HRP-091. If so, choose applicable box(es):

☐ Per section 5.5.1

☐ Per section 5.5.2

☐ Appendix A-10 of the Investigator Manual will not be followed. Explanation of procedures not following Appendix A-10:
✍Click here to enter text.

20.7.3. Justification if non-English speaking subjects will be excluded from the research:[50]
N/A

20.8. Subjects Who Are Not Yet Adults (Infants, Children, Teenagers)

20.8.1. Process used to determine whether an individual has not attained the legal age of consent under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years):[51]

Aim 1: Chart screening

Aim 2: The age of the adolescent will be determined by asking the participant their age prior to conducting the interview and/or usability testing session. We will primarily be asking participants to confirm they meet eligibility requirements prior to setting up an interview and/or usability testing session (i.e., asking parent child's age; chart screening conducted by Seattle Children's staff), however, we will also ask the adolescent before the start of the session.

Aim 3: N/A

Aim 4: Chart screening

20.8.2. Parental permission will be obtained from:[52]

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Neither parent.[53]

20.8.3. Process used to determine an individual's authority to consent to each child's general medical care if permission will be obtained from someone other than parents:[54]
N/A

20.8.4. Assent will be obtained from:[55]

☒ All children.

☐ Some children. Specify: ✍Click here to enter text.

☐ None of the children. Explain: ✍Click here to enter text.

20.8.5. Procedures for obtaining and documenting assent:

Aim 1, 2, & 4: Children 13 and older will review an information sheet online on the survey hosting platform (e.g., REDCap). An assent form will be reviewed by children under the age of 13 years. An opportunity to ask questions with a study team member will be provided to the adolescent. Additionally, the information sheet provided to the adolescent will be the same one provided to their parent, so both are able to read in detail about the adolescent's ability to assent to participate in this study and ask questions. All contact for recruitment will be through the parents (and in the event a child fills out the contact form in Aim 2, we will specifically ask for parent contact information to follow up), and links to REDCap are sent directly to parents, so parents will ultimately have control over whether or not their kids are permitted to enroll. Furthermore, parents who enroll electronically in Aim 4a must provide consent and parental permission before adolescents are approached (see Instrument #3 in Aim 4 REDCap Project Mock-up). Survey links will only be sent to adolescents once their parent submits this form confirming their own agreement to participate and permission for their child to participate.

Aim 3: N/A

20.8.6. Plan for re-approaching children who have reached the age of majority to obtain consent:[56]

Participants who turn 18 during data collection will be re-approached via their parent to obtain consent. The study team will contact the participant, review the information sheet again, and the participant will verbally consent to continue participation.

Participants will not be contacted to obtain consent if they turn 18 after data collection for their involvement in the study ends. We are requesting a waiver of consent for participants who turn 18 once data collection for their involvement in the study ends. Please see justification for this in section 20.10 below.

20.9. Cognitively Impaired Adults/Adults Unable to Consent[57]

20.9.1. Process used to determine whether an individual is capable of consent:

N/A

20.9.2. Individuals from whom permission will be obtained in order of priority:[58]

N/A

20.9.3. Assent will be obtained from:

☐ All of these subjects.

☐ Some of these subjects. Specify: ✍Click here to enter text.

☒ None of these subjects. Explain: There will be no impaired adults/adults unable to consent in this study.

20.9.4. Process for obtaining and documenting assent:[59]

N/A

20.10. Waiver or Alteration of Consent and/or Assent Process[60]

20.10.1. Reasons for requesting a waiver or alteration of informed consent/assent:[61]

We are requesting a waiver of consent for participants who turn 18 once their period of data collection has ended.

20.10.2. Consent/Assent Waiver/Alteration Criteria justifications:[62]

20.10.2.1. The research involves no more than minimal risk to the subjects because:

After data collection is complete, no new information will be collected about participants. This is a minimal risk study with appropriate confidentiality measures in place.

20.10.2.2. The waiver or alteration will not adversely affect the rights or welfare of the subjects because:[63]

Participants will have already assented to be part of the study and have received written study information for all procedures. We will not collect any further information about participants,.

20.10.2.3. The research could not practicably be carried out without the waiver or alteration because:[64]

After data collection is complete, we will not have any further contact with families. We may not be able to locate and therefore get in contact with all families again once the child reaches the age of majority since it may be far removed from study participation, and all eligible participants must be included in the study for results to be meaningful.

20.10.2.4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format because:[65]

Identifiable information for the research is needed so that researchers can perform quality checks.

20.10.2.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

While we do not anticipate this, we will provide subjects with additional pertinent information after participation whenever appropriate.

20.10.3. If the research involves a waiver of the consent process for emergency research, provide sufficient information for the IRB to make it determinations:[66]

N/A

21. Process to Document Consent in Writing

21.1. If consent will be documented in writing (check one):

☐ "SOP: Written Documentation of Consent (HRP-091)" will be followed.

☒ "SOP: Written Documentation of Consent (HRP-091)" will not be followed.
Process of documenting consent:[67]

N/A, Consent will not be documented in writing. We are requesting a waiver of documentation of consent.

Clinicians: do not typically provide written consent to engage with a process like this (surveys, develop tools, etc.), therefore, written consent is not normally required outside of the research or clinical context.

Parents & Children: no information will be provided in the clinical context for this population, and they do not typically provide written consent to engage with materials like these in the study (answer questions in an interview or survey, offer opinions to developed tools). Additionally, parents and children will be allowed to refuse to answer any question they are uncomfortable with, not typically requiring written consent since no questions are absolutely required.

21.2. If consent will not be documented in writing (check all boxes that apply):[68]

☒ A written statement/information sheet describing the research will be provided to subjects.[69]

☐ A written statement/information sheet describing the research will not be provided to subjects. Explain: Click here to enter text.

☐ A consent script will be used.[70]

XXXX

22. HIPAA Authorization and RCW Criteria

22.1. HIPAA Authorization (check all boxes that apply):

☐ The study does not involve the receipt, creation, use and/or disclosure of protected health information (PHI).[71]

☐ HIPAA authorization will be obtained as part of a signed consent form.

☒ The study will access PHI without prior authorization from subjects (including for recruitment purposes – e.g., reviewing the medical record to determine eligibility). *See 21.2 below for required HIPAA waiver/alteration criteria*.

☒ Subjects will review a written statement/information sheet with the appropriate HIPAA language but will not provide a written signature. See 22.2 below for required *HIPAA alteration criteria*.[72]

☐ Other. Explain:[73]

22.2. HIPAA Waiver/Alteration Criteria: [74]

22.2.1. Reasons for requesting a waiver or alteration of HIPAA Authorization:
We may utilize chart screening as a way to identify and recruit participants. As such, we will need to review medical records to determine eligibility for this study. For aims 1-3, we plan on asking Seattle Children's clinicians, an approved Seattle Children's medical professional, or approved Seattle Children's entity (i.e. Clinical Data Analytics) to review patient charts on our behalf to suggest participants for our

study. For Aim 4, the study team will be reviewing provider schedules and patient charts to determine eligibility for the study and to ensure participants are sent and/or respond to subsequent surveys at the appropriate time (e.g., after a follow-up visit). Additionally, we may obtain PHI that pertain to potential participants (i.e., their contact information and confirmation that they fit criteria for inclusion in the study based on their concussion history) prior to when they are enrolled. Some PHI may be also collected via our selected survey hosting platform (e.g., REDcap).

We are also requesting a written signature waiver for Aims 1, 2 and 4. It is expected that most participants will select to participate online for this aim, making collection of written signatures difficult – particularly in the current environment of government ordered shelter in place orders - therefore written signature is requesting to be waived. Some PHI may be collected during this Aim via our selected survey hosting platform (e.g., REDcap) such as zip codes and number of concussions incurred in the past.

22.2.2. The use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:

22.2.2.1. An adequate plan to protect the identifiers from improper use and disclosure:

The following information applies to both the waiver of HIPAA needed for screening medical records and the waiver of written consent: The study team affirms that there is an adequate plan in place to protect identifiers from improper use and disclosure. All study data will be stored on secure servers requiring password access on Seattle Children's servers. Participant names, if collected, will be stored in a separate password protected file accessible only to study staff under the supervision of the Principle Investigator and study Research Scientist.

22.2.2.2. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:

The following information applies to both the waiver of HIPAA needed for screening medical records and the waiver of written consent: All PHI and identifiers will be destroyed at the earliest opportunity consistent with the research protocol. We anticipate that this will mean destroying PHI and identifiers within 9 months of completion of data collection. If a participant chooses not to participate, identifiers will be destroyed within one week.

22.2.2.3. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:

The following information applies to both the waiver of HIPAA needed for screening medical records and the waiver of written consent: The PHI 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.

22.2.3. The research could not practicably be conducted without the waiver or alteration of authorization:

We are requesting a waiver of HIPAA because we will not be able to obtain written signature on an authorization of HIPAA form prior to collecting a limited set of information about potential participants to be used to determine whether or not they meet study eligibility criteria. It is not practical to get HIPAA authorization prior to accessing records for screening because it would make recruitment extremely challenging if we are unable to target participants. Additionally, due to COVID-19 concerns, we plan on recruiting and enrolling participants remotely to minimize the possibility of transmission of the virus, which makes obtaining written signatures on an authorization of HIPAA form extremely challenging..

22.2.4. The research could not practicably be conducted without access to and use of the PHI:[75]

The PHI collected during screening activities is necessary for the research. The research cannot be practicably conducted without the alteration because access to and use of PHI is necessary for screening purposes and given the number of potential participants and that they are spread across the Puget Sound region and potentially beyond, should gatekeeper and snowball recruitment result in self-referral of participants.
Regarding the alteration of the signature requirement, the clinical nature of the study requires that some minimal health information about subjects is included in the data that will be collected.

23. Payments/Costs to Subjects[76]

23.1. Amount, method, and timing of payments to subjects:[77]

Aim 1: For Seattle Children's employees not paid through Seattle Children's payroll, a gift card will be provided to each survey participant. The gift card will be $25 and will come through the form of a Seattle Children's gift card. Participants will receive their gift card in the mail at the completion of their survey and after we receive a de-identified list of names and addresses of those who participated in the survey. Participant compensation for Seattle Children's employees will be paid to their paycheck following receiving a de-identified list from the survey hosing site (i.e., survey responses will not be linked to names).For parent and adolescent participants, each population will be told that they will be entered for a chance to receive one of four $50 gift cards for completion of the 10-minute surveys. Drawing for gift card recipients will occur as soon as all data collection is complete.

Aim 2: A gift card will be provided to each interview and/or usability testing participant (i.e. if a participant completes both tasks, they will a gift card each time). The gift cards will be $50 and will come through the form of a Seattle Children's gift card. Participants will receive their gift card in the mail or via email at the completion of their interview and/or usability testing session..

Aim 3: For Seattle Children's employees not paid through Seattle Children's payroll and non-Seattle Children's employees, a gift card will be provided to each interview and/or usability testing participant. The gift cards will be $30 and will come through the form of a gift card. Participants will receive their gift card in the mail or via email at the completion of their interview and/or usability testing session. Participant compensation for Seattle Children's employees will be paid to their paycheck following their interview and/or usability testing session.

Aim 4: Participants will be compensated at a minimum of three timepoints for survey completion: 1) $25 for completion of a baseline survey, 2) $25 for completion of follow-up survey(s) (up to and including their final clinic visit), and 3) $50 for completion of the 3-month follow-up survey (i.e. 3 months after their initial clinic visit). If participants have more than 5 follow-up visits, they will be compensated an additional $5 for each additional visit for a maximum of 10 visits (i.e. an additional $25). Healthcare providers will be compensated $25 for completing a brief survey.

23.2. Reimbursement provided to subjects:[78]

Participants will be compensated for participating in their aim of the study. See section 23.1 for details on compensation.

23.3. Additional costs that subjects may be responsible for because of participation in the research:[79]

N/A

24. Setting

24.1. Site(s) or location(s) where the research team will conduct the research:

Aim 1: Surveys will be conducted online via a survey hosting site (e.g., REDCap)

Aim 2: Usability testing sessions will be conducted either online, at a location preferred by the participation or at Seattle Children's Research Institute, Seattle Children's Hospital, or a Seattle Children's affiliated clinic.

Aim 3: Interviews will be conducted either online, at a location preferred by the participation or at Seattle Children's Research Institute, Seattle Children's Hospital, or a Seattle Children's affiliated clinic.

Aim 4: Surveys will be conducted online via survey hosting site (e.g., REDCap). If participant prefers, surveys can be filled out on a phone or tablet while waiting for their clinic visit.

24.2. Composition and involvement of any community advisory board:

The study will occur in consultation with an advisory board comprised of up to 10 clinicians. We will identify potential board members through our own colleague referrals. Board members will up to four times (in a group or as individuals) with compensation of $50 per meeting. The role of the advisory board will be to provide feedback about the material development and implementation strategy development process.

24.3. For research conducted outside of the organization and its affiliates:[80]

24.3.1. Site-specific regulations or customs affecting the research:

N/A

24.3.2. Local scientific and ethical review structure:

N/A

25. Resources Available

25.1. Qualifications (e.g., training, education, experience, oversight) of investigator(s) to conduct and supervise the research:[81]

The Principal Investigator is an Assistant Professor at the University of Washington, with expertise in parent and adolescent decision making. She has experience with qualitative and quantitative analysis, staffing, institutional review board management, and budgeting.

The Research Scientist is a PhD graduate from the University of Washington. She has expertise in health communication and has been working with Dr. Kroshus on her other shared decision-making research. She has experience managing participant recruitment, conducting interviews and qualitative analyses, and working on research related to communication about health.

Any and all study staff will be located at Seattle Children's Research Institute.

25.2. Other resources available to conduct the research:[82]
N/A

26. Coordinating Center Procedures

26.1. Coordinating center institution:
N/A

26.2. If Seattle Children's is the coordinating center:

26.2.1. Process to ensure communication among sites:[83]
N/A

26.2.2. Process to ensure all site investigators conduct the study according to the IRB approved protocol and report all non-compliance:
N/A

26.2.3. Process to ensure all required approvals are obtained at each site:
N/A

26.2.4. Process to ensure all sites are informed of any problems and/or interim results:
N/A

27. International Center for Harmonization of Good Clinical Practice (ICH-GCP)

27.1. If you have committed to conducting the described study per ICH-GCP, check this box: ☐[84]

- This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
- Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.
- **If you check the box, upload a current curriculum vitae (CV) for the PI to the "Other Attachments" section of the "Local Site Documents" SmartForm.**

[1] Include information if this protocol is associated with other IRB-approved studies (e.g. is this application the next part/phase of a previously approved application.

[2] In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

[3] Include information on a drug or biologic in this section if: (1) the study specifies the use of an approved drug or biologic; (2) the study uses an unapproved drug or biologic; (3) the study uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition; or (4) data regarding subjects will be submitted to or held for inspection by the Food and Drug Administration (FDA). Only include information on a device in this section if: (1) the study evaluates the safety or effectiveness of a device; (2) the study uses a humanitarian use device (HUD) for research purposes; or (3) data regarding subjects will be submitted to or held for inspection by the FDA. Please note that mobile medical applications may meet the definition of a device – see FDA Guidance.

[4] See the Investigator Manual HRP-103 for sponsor requirements for FDA-regulated research.

[5] Explain what IND exemption category applies to the drug and why. Note that a drug is not exempt from an IND unless all criteria for one category are met. See "HRP-306: Drugs" for more information.

[6] Explain what IDE exemption category applies to the device and why. Note that a device is not exempt from an IDE unless all criteria for one category are met. See "HRP-307: Devices" for more information.

[7] Explain why the device is NOT a significant risk device. A significant risk device means an investigational device that: (a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (b) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

[8] Be sure to indicate if controls will be included and include information about why control arms are ethically acceptable.

[9] Describe all of the research procedures being performed. Be sure to make it clear which procedures apply to each subject population. When applicable, describe how research procedures differ from standard of care and/or affect standard of care. Describe any audio/video recording that will be involved.

[10] Attach all surveys, scripts, and data collection forms to the "Supporting Documents" page.

[11] Include information about the frequency of data collection.

[12] See HRP-001 - SOP – Definitions for definition of banking. Type N/A if not applicable. If the data is subject to NIH Genomic Data Sharing Policies (e.g. you will submit data to dbGaP, NDAR, FITBIR), indicate here.

[13] If applicable, include a list of identifiers that will be banked.

[14] Be general (e.g., researchers' lab, clinic, etc.)

[15] Generally, data and/or biospecimens should be released in a coded, non – identifiable manner.

[16] Include a description of the process used to verify and document that any required approvals have been obtained prior to release of data/biospecimens from the bank.

[17] You can allow for use for broad purposes

[18] This includes putting results and/or data in the subject medical records.

[19] If your population will differ from the representative population where the study will take place (e.g., race, ethnic group, or gender), provide a rationale for the differences.

[20] If you check a box below, be sure to include the additional safeguards associated with the population.

[21] Refer to HRP-416 CHECKLIST: Children.

[22] If the study is minimal risk, explain why. Must also include, as applicable: (1) why direct benefits are anticipated, (2) why risks are justified by anticipated benefit and/or the relationship between risk and prospective benefit compared to available alternatives, (3) why risk represents only minor increase over minimal risk, (4) how study procedures are reasonably commensurate with those inherent to the child's actual or expected conditions, (5) whether the interventions/procedures are likely to yield generalizable knowledge about the participant's condition and why it is of "vital importance" to understanding or amelioration of the participant's underlying disorder or condition, and (6) an explanation of what alternative methods/approaches were considered to make the above assessments (as applicable).

[23] This population may be wards of the state or any other agency, institution, or entity. Refer to HRP-416 CHECKLIST: Children, Section 6, for additional guidance on required considerations for this population.

[24] This refers to both cognitive impairments and adults who are incapacitated for any other reason. As applicable, refer to HRP-417 CHECKLIST: Cognitively Impaired Adults.

[25] Refer to HRP-413 CHECKLIST: Neonates and HRP-414 CHECKLIST: Neonates of Uncertain Viability.

[26] Refer to HRP-412 CHECKLIST: Pregnant Women.

[27] Refer to HRP-415 CHECKLIST: Prisoners

[28] Indicate how you will ensure that there is no coercion or undue influence

[29] A subject is considered "enrolled" when they consent to be in the study.

[30] Only applicable for multisite studies.

[31] i.e., numbers of subjects excluding screen failures.

[32] Payment for participation is not considered a benefit.

[33] For example, data will be double entered, data will be reviewed by another study team member to ensure accuracy, etc.

[34] If your study is multisite and there are differences in how confidentiality will be maintained by the coordination center and our local site, this should be explained in this section (e.g. local site will have samples that are linked to a person's name, but the coordination center will only receive coded samples without any links). Confidentiality regarding use of Social Media will be explained in a protocol section below.

[35] Privacy refers to persons and their interests in controlling the access of others to themselves. For example, based on privacy interests, people want to control the time and place where they give information, the nature of the information they give and who receives and can use the information.

When providing a response, consider the subject population and nature of the study. 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 building.

[36] Applicable for studies that present more than minimal risk.

[37] Include information about who (describe in terms of role or group) will review the data.

[38] This should be specific to the social media you are using for the research.

[39] All communications that are directed towards subjects and specific to a particular study will require prior IRB review and approval. All non-IRB reviewable communications can be described in general terms by category – news stories, relevant publications – and representative examples of each can be provided.

[40] Applicable if the research involves more than minimal risk to subjects. If minimal risk, this section is N/A.

[41] If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) those methods should also be described here.

[42] For example, subjects will be initially approached in a private room or a letter rather than a postcard will be sent when the study name may disclose health information about the potential subject.

[43] For example: medical records, CIS, clinical databases, other study records. If the study will access PHI for recruitment purposes without prior authorization from subjects, please address this in the HIPAA Authorization section below.

[44] Attach copies of these documents to the Recruitment Materials section of the study SmartForm. For printed advertisements, attach the final copy. For online advertisements, attach the final screen shots (including any images). When advertisements are taped for broadcast, send the final audio/video tape to IRB@seattlechildrens.org. You may attach the wording of the advertisement to the SmartForm prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

[45]Include how you will ensure that subjects and/or their parent/legally authorized representative have sufficient opportunity to discuss and consider whether or not to participate in the research. .

[46] For example, the consent discussion will take place in a private room.

[47] This section describes the way(s) in which the processes for this study will not follow Seattle Children's SOP.

[48] See HRP-090, HRP-091, and Investigator Manual HRP-103 for more information.

[49] Note the Short Form Consent may only be used when certain conditions are met. See HRP-091 for requirements for Short Form consent form use.

[50] Seattle Children's IRB prohibits the exclusion of non-English speaking populations from research unless there is sufficient justification for the exclusion. See Investigator Manual HRP-103 for more information.

[51] For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children." The age of majority in

Washington is 18; however, sometimes younger children have ability to consent for certain types of care (e.g. sexual reproduction/health; mental health; drug/alcohol treatment). For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to SCH to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[52] For minimal risk studies and greater than minimal risk studies that offer a prospect of benefit, the IRB generally requires one parent to provide permission for the child to participate.

[53] If parental permission will not be obtained, please address this in the Waiver or Alteration of Consent Process below.

[54] See HRP-013 for more information.

[55] The IRB generally follows the following guidelines for written assent: children 7-12 should provide written assent on the "simple" assent form (HRP-502G); children 13-17 should provide written assent by co-signing the parental permission form (HRP-502A). The IRB will consider other assent scenarios (e.g. verbal assent for some or all children; not requiring assent for some or all children; or waiving assent): please provide details about the plan for your study. See HRP-090 and HRP-416 for more information on waiving assent and when assent is not necessary.

[56] See Appendix A-13 of the Investigator Manual HRP-103 for requirements for re-consent at age 18. If you think you meet the conditions for a waiver at 18, please address this in the Waiver or Alteration of Consent Process below.

[57] See "HRP-417 Cognitively Impaired Adults" for further information.

[58] For example: durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. If you are following HRP-013 in order to make this determination, simply state that in this section. For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to Washington to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[59] The IRB may allow the person obtaining assent to document assent on the consent document.

[60] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[61] For example: consent/parental permission will not be obtained, required information will not be disclosed, the research involves deception, waiver for participants who turn 18, waiver for information collected about a non-present parent, or other waivers as necessary.

[62] The IRB needs to make all the waiver findings and key to this determination is that the IRB understand why it is not practicable to do the research without a waiver of consent. You need to provide a rationale in order for the IRB to consider whether the waiver criteria are met. See "HRP-410: Waiver or Alteration of the Consent Process" for further information.

[63] Possible reasons might include: a) you are not collecting information that could put subjects or their families at harm, e.g., affect eligibility for insurance, employability, stigmatization; b) you are not collecting information that would alter or affect the subject's care; c) any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

[64] Possible reasons could be: a) inability to locate families because of the lengthy time period over which the records/samples were created; b) many of the subjects whose records, data, or biospecimens will be used may have died and contacting the families about the research could cause harm and anguish to families; c) all eligible patients must be included in the study for the results to be meaningful.

[65] For example, identifiers are necessary, so that researchers can perform quality checks or identifiers are necessary to link data from multiple sources.

[66] See "HRP 419: Waiver of Consent for Emergency Research" for further information.

[67] This section describes the ways in which the procedures will not be following Seattle Children's SOP.

[68] See "HRP-411: Waiver or Written Documentation of Informed Consent" for further information.

[69] An information sheet template can be found in the Click IRB Library and should be attached to the consent form of the study SmartForm. For internet research, the information sheet can be translated to an on-line format, if desired.

[70] The IRB sometimes requires a script if you are having the consent conversation over the phone rather than in person. Templates for a consent script are available on the IRB website on the Participant Recruitment page and should be attached to the study SmartForm.

[71] PHI is health information that is also identifiable because it includes one or more of the 18 HIPAA identifiers. See Investigator Manual HRP-103 for the list of HIPAA identifiers.

[72] If your study involves using or creating PHI and your only contact with participants is online, you can request an alteration of HIPAA authorization to remove the signature requirement. As an alternative to a waiver of documentation of consent and an alteration of HIPAA authorization, you must demonstrate that the electronic consent signatures are compliant with applicable state/international law (in Washington, see RCW 19.34.300).

[73] For example: altering HIPAA elements for international research.

[74] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[75] Possible reason could be: the nature of the research is specific to individuals' health and requires access to individuals' health records.

[76] See "HRP-316: Payments" for further information.

[77] Methods of payment include check, ClinCard, gift cards, etc. Provide details on who will be the recipient of the payment (parent or child).

[78] Reimbursement is used when the subject is paid back for travel expenses such as transportation, food, childcare, or lodging. Reimbursement is generally distributed to person who incurred cost (usually parent) and requires receipts to be submitted.

[79] This could include things like fuel/transportation costs, parking, and/or childcare.

[80] Type N/A if this section does not apply.

[81] Provide enough information to convince the IRB that the principal and/or co-investigator(s) are appropriately qualified to conduct and supervise the proposed research. When applicable, describe their prior clinical experience with the test article or study-related procedures, or describe their knowledge of the local study sites, culture, and society.

[82] For example, as appropriate: (1) Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? (2) Describe the time that you will devote to conducting and completing the research. (3) Describe the facilities in which the research will be conducted. (4) Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research. (5) Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

[83] Including communication between sites of current study document versions and modifications.

[84] If you check the box, you are required to conduct your study according to the principles outlined at https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html.