INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE

The Effect of Screen Time on Recovery from Concussion

2. EXTERNAL IRB REVIEW HISTORY*

None

3. PRIOR APPROVALS:

Prior Approvals: We have secured approvals from the Emergency and Pediatrics Department at UMASS.

Conflict of Interest (COI): None of the study Investigators have a COI with this research.

Clinical Engineering Department:
N/A

Biohazardous Agents:
N/A

Radiation:
N/A

4. OBJECTIVES*

This study seeks to prospectively examine the effect of screen time on the duration of post-concussive symptoms. We hypothesize allowing screen time as tolerated in the first 48 hours of recovery will cause the symptoms to be prolonged.

5. BACKGROUND*

There are 2.8 million emergency department (ED) visits annually for traumatic brain injury in the United States.[1] The 2016 Consensus Statement of the 5th International Conference on Concussion in Sport favors a period of 24 to 48 hours of cognitive and physical rest in the acute phase of concussion recovery; however, there is no specific recommendation for the use of screen time during this period.[2] The ability to watch television, use phones, and play video games is a very common question of parents and patients. The is a dearth of teenage-acceptable substitute activities that maintain rest – listening to music, coloring, books on tape? Some clinicians favor screen time, saying it is a form of cognitive rest and one of the few options for a pediatric concussion sufferers to occupy themselves during the initial period of inactivity. Others strongly caution against the use of screen time arguing it is excessive visual

stimulation and cognitive effort. Some doctors offer recommendations on specific types and durations of screen time, for example allowing television but not video games, or limiting communications to a certain number of text messages daily.[3,4] To the best of our knowledge, there are no randomized controlled trials looking at the specific effect of screen time on concussive symptoms.

This study will prospectively examine the effect of screen time on recovery from concussion. Patients 12 to 25 years of age presenting to the ED with a concussion will be randomized to allow for screen time as tolerated or to abstain from screen time for the first 48 hours of recovery. The amount of screen time use and duration of concussive symptoms will be assessed through daily surveys.

6. INCLUSION AND EXCLUSION CRITERIA*

Inclusion Criteria: We will include individuals, including pregnant women, who are presenting to the emergency department with a traumatic head injury sustained in the last 24 hours that have a concussion as defined by as defined by the Acute Concussion Evaluation tool (ACE-ED)[5] and are:

A) Between 12 and 25.99 years of age
B) English-speaking
C) Subject (and parent/guardian when applicable) is able and willing to provide informed consent and assent

***Exclusion Criteria*:** We will exclude individuals who have a Glasgow Coma Scale score of 13 or less; have brain abnormalities on imaging; have severe preexisting neurological conditions; have significant developmental delay; are intoxicated; or require neurosurgical intervention, intubation, or hospital admission as well as individuals who:

A) Do not meet the age criteria;
B) Are non-English speaking;
C) Are prisoners;
D) Are unable or unwilling to provide informed consent;
E) Are under the age of 18 and do not have a parent/guardian with them who is willing and able to consent.

7. STUDY-WIDE NUMBER OF SUBJECTS*

N/A

8. STUDY-WIDE RECRUITMENT METHODS*

N/A

9. STUDY TIMELINES*

Participants will be part of this study for the time it takes to consent and complete questionnaires at enrollment,daily surveys for 10 days, and a survey 30 days and 6 months post-enrollment (approximately 60 to 100 minutes in total).

We anticipate it will take 18-24 months to enroll all study subjects. This study should be completed by September 2020.

10. STUDY ENDPOINTS*

Volunteers' participation in the study ends after completing the email or paper survey 6 months post-discharge.

The primary outcome measure is the duration of concussive symptoms. Secondary outcomes include the number and severity of specific symptoms each day, amount of screen time use, days until return to school/work and sports, effect of specific types of screen time (i.e. video games) on concussive symptoms and duration.

11. PROCEDURES INVOLVED*

Recruitment: *See Section 24*

Consent: *See Section 30*

Main Intervention:

Following consent in the emergency department, subjects or parents will be asked to complete a questionnaire of demographic information (Appendix A) and the ACE-ED (Appendix B). The study staff who enrolls the participant will either enter the participant's answers directly in REDCap or on paper. When handwritten, these responses will be stored in a locked box in the emergency department until study personnel enter it into REDCap. The patient will be randomized to either allow for screen time as tolerated for the first 48 hours or abstain from screen time for 48 hours. The patient will be randomized upon opening a sealed envelope, which contains the subject's study number and study group. Subjects will be discharged with a paper log book to help keep track of screen time, schoolwork/work, and exercise over the next 48 hours (Appendix C). Study staff will write the corresponding dates on the log book at enrollment. Study Participants will also receive standard ACE-ED discharge instructions modified with the study group-specific recommendations regarding screen time (Appendix D).

Subjects with the help of parents if applicable will be asked to complete daily surveys for 10 days.

Day 1 to 3 post-discharge: Screen time Survey (Appendix E) and PCSS (Appendix G)

Day 4 to 10 post-discharge: Activity survey (Appendix F) and PCSS (Appendix G)

Subjects will then be sent a PCSS and survey at day 30 (Appendix H) and 6 months (Appendix I) after enrollment.

We will conduct an initial feasibility study comparing two methods for daily surveys – daily email surveys and a pre-addressed paper packet. The questions for each method are identical. We will recruit ten patients to trial each method and random assign 5 to each study group within each survey method. Based on the success of these two methods, we will either choose the superior method or retain both as an option for subjects in the larger study.

For the email surveys, we will use the REDCap Database in "Survey" mode to track recruitment and collect all relevant data. The email address field in REDCap will automatically generate 10 days of daily surveys (Appendix E, F, and G), a 30 day survey (Appendix H), and 6 month survey (Appendix I). If a subject has not returned a survey for the previous three consecutive days, they will be removed from the email list. To avoid being intrusive, no more than 2 reminder emails will be sent daily during the study period. Subjects and/or guardians will be emailed a REDCap survey at 8 a.m. Subjects who have not yet completed the daily survey will get an email and/or phone call reminder to complete the survey between 2pm and 8pm.

For the paper surveys, the subject is given a packet with the surveys (Appendices E, F, G) printed out for 10 days stapled together with the study ID number at the top of each page. The study staff enrolling the patient will write the corresponding dates for surveys on the packet. The subject will be asked to complete the daily surveys and mail back the packet after day ten. The subject will be sent the 30 day and 6 month follow up surveys. Subjects will be provided with stamped self-addressed envelopes for all surveys to the PIs office at UMASS Memorial, University Campus. The PI will input the data to REDCap and destroy the original documents. With subjects' permission, they will receive up to 4 follow up phone calls from study staff during the study period to promote retention, answer questions, and offer replacement packets by email if data is lost within first two days of study enrollment.

We wish to send 30 day and 6 month surveys to subjects already enrolled in the study. The survey will be sent by email through REDCap or USPS mail in the same fashion as the daily surveys were to participants. If subjects have not completed the survey within 2 days, they will be sent a reminder email. Subjects will not be contacted beyond the two potential emails for each survey.

Subjects enrolled in the study following this amendment will be notified at enrollment of a 30 day and 6 month follow up survey.

12. DATA AND SPECIMEN BANKING*

N/A

13. Data Analysis and Management*

Sample Size and Power Calculation

Our primary outcome is post-concussive symptoms, which are measured by the PCSS scale. Based on previous research[6], we hypothesize that our intervention will improve patients' score by 12 points in total PCSS (equivalent to a moderate effect size, based on an estimated SD of 22). Using G-Power program (means procedure) with α=0.05 (two-sided), power (1-β) =0.80, the calculated sample size is 106 (53 for each study group).

Data Analysis Plan

The outcome variable is the duration of concussion symptoms. The main predictor variable is screen time-allowed versus screen time-abstinent instructions. For univariate modeling, we will use Kaplan-Meier analysis with log-rank tests of significance to evaluate the effect of screen time on time to symptom resolution. To evaluate the effect of other potential predictor variables on symptom duration, we will construct a multivariate Cox proportional hazard model that includes cognitive activity, exercise, age, gender, number of previous concussions, history of prolonged concussion, total initial PCSS score, amnesia at time of injury, and loss of consciousness at time of injury. To further assess for the potential effect of age, we will independently perform these analyses separately for 2 separate age categories: pediatric (12–18 years) and adult (18–25 years).

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

This is a minimal risk study. Any unanticipated adverse events will be reported in accordance with **HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements**.

Data will be analyzed by the primary investigator after the first 50, 100, 150 and 200 enrolled subjects. The study will be terminated if either group demonstrates a significant difference in duration of symptoms as defined by a significant ($p < 0.05$) Mann-Whitney U Test comparison of a median time difference greater than 2 days until concussion recovery (PCSS $\leq$ 7).[6]

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

N/A

16. RISKS TO SUBJECTS*

We do not foresee any serious risks for the subjects. There is a risk that utilizing or not utilizing screen time during the acute phase of recovery from concussion may have an effect of the duration or the magnitude of post-concussive symptoms. There is no data on how screen time alone affects recovery from concussion, so we are unsure which group, if any, will have worse or more prolonged symptoms. We anticipate the effect, if present, will be minimally intrusive as the majority of concussions resolve in less than 10 days.[6]

There is a risk that the screen time abstinent group may fall behind in emails, conversation with peers, and completion of work (which is cautioned against in concussion recovery). This may lead to a greater feeling of social isolation or stress.

Although we will take caution to ensure data security and protect PHI, there is always a risk of a data breach. Only registered study personnel will have access to the REDCap database. For the email surveys, subjects and parents will be entering the data into REDCap from their home computer or mobile phone, which may be an unsecured network or device. For the paper surveys, the study ID# and survey responses will be travelling through USPS mail and has a minimal risk of being misplaced. No identifiers except study ID will be on the paper surveys. Sensitive information that could be obtained if REDCap data was hacked includes names, dates of birth, phone numbers, email address, and medical history. We will attempt to minimize this risk by only entering data into REDCap and keeping study identifiers separate from deidentified data within REDCap.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

Subjects will be given thorough discharge instructions with up-to-date treatment recommendations for concussion. The act of keeping a log and answering survey questions will assist subjects in evaluating their own concussion symptoms and compliance with prescribed cognitive and physical rest, which may help them guide their own recovery with the assistance of their primary care physician.

Subjects will be given a $20 gift card if they complete the majority of the initial 10 days of online surveys.

18. VULNERABLE POPULATIONS*

Children: This research is minimal risk and will involve children between 12 and 17. Permission will be obtained by one or both parents or guardians depending on who is present in the emergency department at the time of consent. If one parent does not wish for the child to participate, the child will not be enrolled. No other persons except the parent or legal guardian may consent the subject. Patients in state custody will not be offered participation.

All participants in this study under 18-years-old will be asked for signed assent and the study will be explained in age-appropriate terms (see Appendix H). Any child who does not wish to participate or demonstrates signs of unwillingness to participate as perceived by the parent/guardian or enrollment personnel will not be enrolled.

Pregnant Women: Pregnancy status will not be specifically asked as part of this research. Therefore, pregnant women may be included in the study unless criteria are not met or they choose not to participate. Inclusion does not pose any known additional risks to pregnant participants or fetuses. We will not be providing guidance or advice regarding pregnancy management.

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19. MULTI-SITE RESEARCH*

N/A

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*

N/A

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

We will not be sharing research results with study participants.

22. SETTING

This study will take place in the pediatric and adult emergency departments at the UMASS Memorial-University Campus and the emergency department at the UMASS Memorial-Memorial Campus.

23. RESOURCES AVAILABLE:

Resources Available:

The Emergency Medicine Research Division: This division supports research activities in a diverse array of basic science and clinical topics. Monthly meetings are scheduled for the core department Investigators to review ongoing protocols and to advise and support younger faculty.

Study Staff:

All members are up-to-date on CITI certification and are aware that this training must be renewed every three years. They will conduct this research in accordance with the most up-to-date IRB-approved protocol.

Prior Study Staff training and experience will allow for accurate interpretation of medical records and data abstraction.

The PI will hold conferences for the emergency and pediatrics department to review current concussion guidelines and offer recommendations for standard discharge instructions in keeping with the 2016 Consensus in Sport guidelines. The PI will review the study protocol and enrollment process.

Principle Investigator (PI): The PI is a pediatric emergency physician, boarded in pediatrics with a subspecialty board in pediatric emergency medicine. He has served as principal investigator on three prior studies at other institutions, two retrospective and one prospective. The last study was a prospective study of carbon monoxide exposure in

ice hockey players, which took place in the community under oversight and approval of the Boston Children's Hospital IRB. He will be responsible for personally conducting and supervising all aspects of the study including, but not limited to: design, execution, recruitment, retention, results analysis, preparation of a manuscript(s) and monitoring Research Assistants/Coordinators. He will ensure all Study Staff are provided with the most up-to-date research protocol, train all Study Staff to perform the necessary tasks, and monitor their progress to ensure they are following said protocol. He will also be responsible for regulatory requirements and will be available at all times to assist Staff with any questions or concerns they may have

Co-Investigators (Co-Is): The Co-Is will be current UMASS attending physicians, resident physicians, or medical students. The Co-Is will assist the PI with all aspects of the study including, but not limited to: design, execution, recruitment, subject retention, results analysis, preparation of a manuscript(s) and monitoring Research Assistants/Coordinators.

Research Assistants (RAs): The RAs will have basic training in research methods and human subjects research, as well as at least a bachelor's degree in a human science field or equivalent. They will be trained by the PI to complete all aspects of the study including, but not limited to: recruitment, retention, follow-up and data handling.

Research Coordinators (RCs): In addition to the responsibilities described for RAs, the RCs will assist with regulatory requirements and communications with the IRB.

Statistician: Will assist in sample size calculation, survey design, data analysis, and data presentation.

24. LOCAL RECRUITMENT METHODS

Feasibility

A Pulsecheck inquiry yielded about 350 patients aged 12 to 25 annually diagnosed with concussion in the ED in 2015 and 2016. As we anticipate needing about 120 subjects (see **Section 13**) but anticipate a significant loss to follow up rate, we believe the necessary sample size can be achieved within one to two years.

Recruitment Procedures:

Potential participants presenting to the emergency department with head injury will be identified by an investigator, research assistant, or clinical staff. Study Staff will query the ED tracking system (EPIC) to identify eligible participants. We also hope to create a "Best-Practice Advisory" for EPIC to help practitioners remember to recruit patients.

Study Staff will obtain the potential participant's name, ED bed location, and treating physician's name from the tracking system. With permission from the attending physician, the patient will be approached about study participation. Once deemed potentially eligible from age and chief complaint, the potential participant will be given a Study ID#.

After the potential participant has been evaluated, treated, and deemed medically stable, with permission of the attending physician, a member of the Study Staff will approach them regarding this research. At that point the potential participant will be given a study ID#. The Study Staff member will ask for the individual's (and, if applicable, guardian's) permission to explain our study and then will be offered the opportunity to participate. Identifying information (Appendix A) and the results of the administered survey (Appendix B) in the emergency department will be entered directly into REDCap, if available to the enroller, and, if not, on paper to be placed in a locked box in the emergency department until Study Staff can enter the data into REDCap.

Destruction of Identifiers:

For individuals who turn out to be ineligible based on exclusion criteria (see **Section 6)** or not meeting the definition of concussion on ACE-ED (Appendix B) or those who decline to participate, identifiers will be deleted from REDCap and/or the paper copies will be shredded within 48-hours of discharge from the ED.

For individuals who consent to the study, identifiers will be linked to study survey results for a limited period of time. Appendix A will serve as the master code and patient identifiers can only be accessed on Red Cap by approved Study Staff. If the patient was initially enrolled on paper, the paper will be shredded upon entry of Appendix A into REDCap within 48 hours of ED discharge. Identifiers will be deleted following the participant's completion in the study 10 days post-discharge.

Compensation:

Study participants will be compensated for their time with gift cards for a total value of $20. The gift cards will be distributed through an emailed weblink following completion of the day 10 email survey or receipt of the survey packet by mail. If a participant is completing paper surveys and does not have an email address, the gift card will be mailed.

25. LOCAL NUMBER OF SUBJECTS

We anticipate screening 300 subjects, enrolling 200 and retaining 120.

26. CONFIDENTIALITY

Procedures to Secure the Data:

Coding: Upon identification for possible enrollment, potential participants will be given a Study ID#. When possible, participants will be entered directly into REDCap at recruitment by a member of the Study Staff on an institution-issued tablet computer or computer-on-wheels. If

necessary, Appendix A and B will be completed on paper. Following completion on paper, they will be placed into a locked box in the emergency department accessible only to Study Staff. When the paper forms have been entered into REDCap, they will be shredded and disposed of through the hospital HIPAA disposal system. Appendix A will serve as the master code linking patient identifiers with the Study ID#. It can only be accessed only on Red Cap by approved Study Staff. Appendix B-G will be marked with the participant's Study ID# only and can only be accessed through REDCap by study personnel.

Access: Only members of the Study Staff (PI, Co-I, RA, RCs) will have access to the Red Cap study data.

Storage: As mentioned in *Section 24*, we will be using REDCap to track recruitment and collect all relevant data. REDCap requires Study staff to log in using their credentials and password. Upon completion of data collection, de-identified survey responses will be exported to a statistical software package (SPSS or STATA). These spreadsheets will be stored on secure, password protected UMass Memorial servers which also require authorized Study Staff to log in using their credentials and password.

Paper surveys will be stored in a locked box in the emergency department until they are entered into RedCap, at which point they will be destroyed.

Destruction: As mentioned in *Section 24*, individuals ineligible or unwilling to participate in the study will be deleted from REDCap and if relevant the paper copies, stored in a locked box will be shredded within 48-hours of discharge from the ED.

For individuals who consent to the study, identifiers will only be linked to study survey results through Appendix A for a limited period of time. Identifiers will be deleted from Red Cap within 24 hours following the participant's completion of the study 6 months post-discharge. Completed surveys (Appendix B-G) will be linked by Study #s only. In accordance with **HRP-800**, completed surveys will be stored for 3 years following completion of this research.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

We will use a HIPAA waiver of authorization to identify potential participants.

Individuals will be informed that their participation is voluntary and refusal or withdraw of participation will not involve any penalty or loss of benefits to which they are otherwise entitled. The consent process and initial surveys will be conducted in a private location (typically the ED room of the patient). Participants will be informed that they can skip any survey questions that they feel uncomfortable answering.

Following consent, a signed HIPAA Authorization will be obtained to access and record information from the participant's EMR. This information will be limited to information directly related to the study.

28. Compensation for Research-Related Injury

N/A

29. Economic Burden to Subjects

There will be no economic burden to participants due to participation in this study.

30. Consent Process

Once permission has been obtained from the potential participant's treating attending physician, he or she will be approached by a member of the Study Staff regarding consent. Only Study Staff with prior approval who have reviewed **HRP-802 Informed Consent** and **HRP-021 POLICY: Legally Authorized Representatives, Children, and Guardians** will be obtaining consent.

A member of the study team will obtain consent for all patients and assent from all minors. This process will occur in a room that is private away from other patients or people. All patients under the age of 18 will require assent and parent or guardian consent. Because the study is survey-based and is minimal risk, consent will only need to be obtained from one parent/guardian. Children aged 12-17, will be given an assent form to sign, and the study will be described to them in easy to understand terms. **HRP-021 POLICY: Legally Authorized Representatives, Children, and Guardians** determines which individuals in the state meet the definition of "children."

All of the potential risks, reasoning, and goals of this research will be explained to each individual prior to obtaining consent and assent when applicable. They will be informed that enrollment is voluntary and declining to participate will not affect their treatment. Ample time will be given to answer any questions and they will be informed that they may opt out of this voluntary study at any point. If there are signs of unwillingness or a child chooses not to provide assent, he or she will not be included in the study. Participants will be offered copies of all **Signed Forms** and given Study Staff contact information (**Appendix I**). They will also be informed that they can skip any survey questions that they feel uncomfortable answering.

31. Process to Document Consent in Writing

We will be obtaining informed, written consent for this study. Study Staff will have participants sign the **Consent** document and **Assent** document (when applicable) according to **HRP-803 Documentation of Informed Consent** and the **HRP-021 POLICY: Legally Authorized Representatives, Children, and Guardians**

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32. DRUGS OR DEVICES

N/A

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2. McCrory P, Meeuwisse W, Dvorak J, et al. Consensus statement on concussion in sport—the 5 th international conference on concussion in sport held in Berlin, October 2016. *Br J Sports Med*. 2017;(October 2016):bjsports-2017-097699. doi:10.1136/bjsports-2017-097699.
3. Brown NJ, Mannix RC, O'Brien MJ, Gostine D, Collins MW, Meehan WP. Effect of Cognitive Activity Level on Duration of Post-Concussion Symptoms. *Pediatrics*. 2014;133(2):e299-e304. doi:10.1542/peds.2013-2125.
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