

**PARTNERS HUMAN RESEARCH COMMITTEE  
PROTOCOL SUMMARY**

**Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.**

**PRINCIPAL/OVERALL INVESTIGATOR**

Kristian Olson, MD, MPH (PI)  
Yonatan Keschner, MD (CO-I)  
Ali Raja, MD, MBA, MPH (CO-I)

**PROTOCOL TITLE**

Assessing the experience and effectiveness of a novel anti-fog polymer coating in protective eyewear.

**FUNDING**

Kraton Polymers LLC.

**VERSION DATE**

12.14.20

**SPECIFIC AIMS**

Concisely state the objectives of the study and the hypothesis being tested.

To conduct a randomized, cross-over study assessing the experience and effectiveness of a novel, sulfonated anti-fog polymer in protective eyewear.

**BACKGROUND AND SIGNIFICANCE**

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Personal protective equipment (PPE) must be worn while caring for all patients during the current COVID-19 pandemic in order to prevent the contagious spread of infection. Eye protection is essential and is a mandatory component of the PPE that must be worn for all patient encounters. Current eyewear is problematic due to frequent fogging. This problem is greatly exacerbated due to healthcare providers need to wear face masks that directs humidified exhaled air upwards towards their eyewear. This problem is not only annoying to the wearer, but impacts their vision and can lead to safety issues. Additionally, it has been found that many providers do not comply with the eye protection mandate due to fogging. Furthermore, many providers have been purchasing their own, non-approved protective eyewear. Many brands purport to be anti-fog, which is often an inaccurate claim.

We have identified a novel, sulfonated polymer that appears to provide superior anti-fog properties to eyewear. This polymer is produced by Kraton Corporation, a polymer company. We will apply this novel polymer to the protective eyewear that is currently in use at MGH. Prototypes of this anti-fog coated eyewear have been produced, and pre-clinical feedback has demonstrated spectacular performance.

### **Demonstration of anti-fog coated vs non-coated goggle**

**Non-coated section**

**Anti-fog coated section**



## RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

We will conduct a prospective, randomized, cross-over study of N=50 individuals. Study participants will involve healthcare providers in the MGH Emergency Department, including physicians, physician assistants, and registered nurses. The study will be a randomized, cross-over design, where the participant will be given either a standard goggle or anti-fog coated goggle, and then switch to the other pair after a set time. The participant will wear each goggle type for 2 hours. At the end of each 2-hour period, the study participant will complete a survey (see Appendix A). The survey will measure the participants experience wearing both types of goggles in order to determine if there is a significant difference between the two types of goggles. Specifically, we would like to measure the frequency of fogging, how fogging limited their ability to perform essential tasks, how it may have impacted their ability to care for patients, and their ability to comply with eye protection standards. All participants will be screened, consented and enrolled by trained ED research assistants (RAs). Survey data will be de-identified and collected through RedCAP.

### Inclusion criteria:

- Physicians (Attendings, Fellows, and Residents), Physician Assistants, and Registered Nurses.
- Providing care to patients in the MGH Emergency Department

### Exclusion criteria:

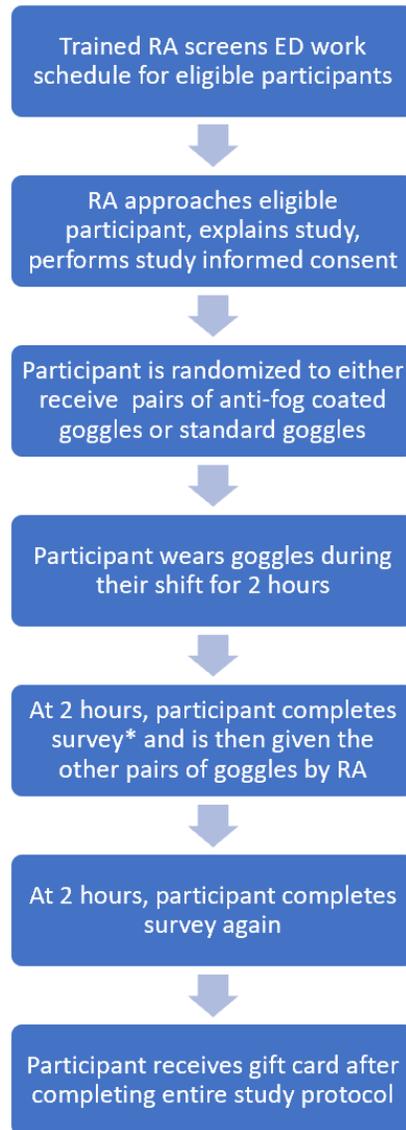
- Wear corrective eyeglasses
- Unable to wear protective eye goggles
- Prior participation in this study

After completing both surveys, participants will be compensated \$20 in a gift card to MGH Coffee Central.

The participant may elect to withdraw at any time during the study. Any withdrawals from the study will be tallied in anonymous fashion by the study personnel. Participation in this study does not preclude the subject from participating in any other research studies.

Briefly describe study procedures. Include any local site restrictions, for example, “Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study.” Describe study endpoints.

### Study Flow Diagram Overview:



\*Survey will be completed through RedCAP. Survey questions may be found in appendix.

### Detailed study procedures:

1. RA's identify eligible participants from daily ED work schedule.
2. RA's block-randomize, via computer based random number generator based on number in each list. Each list will contain eligible Physicians, Physician Assistants, and Registered Nurses, and approach eligible participants.

3. RA describes purpose of study and summary of protocol, requests participation, and performs informed consent.
4. RA uses computer randomizer to determine if an anti-fog goggles or standard (uncoated) goggles are distributed first.
5. RA provides new pair(s) of coated or uncoated goggle(s) to study participant per randomization.
6. Participant uses study protective goggles (eyewear is mandated per MGH PPE policy) for two hours.
7. After two hours, participant is approached (at a time that does not interfere with clinical duties). Survey is completed by study participant through RedCap.
8. First pair of study goggles are collected and stored for disposal in designated receptacle. Participant is then given other pair(s) of goggles.
9. Participant, again, uses study protective goggles (eyewear is mandated per MGH PPE policy) for two hours.
10. After two hours, participant is approached (at a time that does not interfere with clinical duties). Survey is completed by study participant through RedCap.
11. RA provides \$20 Coffee Central gift card to participant after completing the second survey.

Of note: If the participant ever requests a replacement pair(s) during the study period, the RA will be able to provide them with a replacement. If the study participant is unable to use the goggle or is dissatisfied with the study goggle (anti-fog), the study participant will be provided with the standard (not anti-fog) goggle and be asked to complete survey at this time. Study participants can withdraw from the study at any time.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Not applicable.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

We will minimize risks to potential participants by ensuring anonymity during the enrollment procedures. There will be no PHI collected for the purpose of this study. All study data (including survey data and participant information, such as role and gender) will be completed on a secure Partners tablet computers or desktop computers. Tablets and results will be secured using MobileIron and password protected.

Safety goggles utilized (coated and uncoated) are equivalent to the model that are in current use, and, as such, will provide equivalent protection.

In addition, RA will provide new, clean goggles to participants with gloved hands and will clean tablet surfaces (used for survey collection) by the standard hospital cleaning protocol before providing to participants.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Study participants will be able to leave the study at will, at any time. If study participants are having difficulty with the anti-fog coated protective eyewear (e.g. problem with fogging, distorted vision, etc), participant will immediately be given the standard eyewear (control) that is currently being used in the department. We will also be able to provide replacement eyewear to participants (e.g. participant misplaces or soils their given pair) at any time during the study.

#### **FORESEEABLE RISKS AND DISCOMFORTS**

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

There should not be any large risks or discomforts to the subjects. The study will be using the current standard protective eyewear distribute to healthcare providers in the ED. The only difference between the pairs, is that one will be coated with an anti-fog coating. The coating does not cause any safety or health concerns. This polymer has been used in consumer products for a long time, including diapers. The risk of harm due to the anti-fog coating is minimal. Please see Kraton Safety Data Sheet for more information.

#### **EXPECTED BENEFITS**

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

We anticipate that this study will demonstrate increased satisfaction and ability to safely perform clinical duties while wearing new, anti-fog coated eye protection. We expect these anti-fog coated goggles to be superior than what is currently being used in the hospital.

### **EQUITABLE SELECTION OF SUBJECTS**

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

We will never exclude individuals based on gender, ethnicity, religion, sex or race. We anticipate enrolling study participants that will mirror the demographics of the healthcare providers that work in our emergency department.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

All healthcare providers (physicians, physician assistants, and nurses) who work at the MGH emergency department speak English.

For guidance, refer to the following Partners policy:

Obtaining and Documenting Informed Consent of Subjects who do not Speak English

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Non-English-Speaking-Subjects.pdf>

### **RECRUITMENT PROCEDURES**

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

1. RA's identify eligible participants at the beginning of each shift from staffing lists in the ED.
2. RA's block computer randomize eligible MDs, Physician Assistants, and RN's and approach at least one in sequential order of blocks until at their research shift capacity.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

A \$20 give card to Coffee Central will be provided to all participants after they complete the study.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf>

Guidelines for Advertisements for Recruiting Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf>

Remuneration for Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Remuneration-for-Research-Subjects.pdf>

## CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

We plan on obtaining verbal for this study from study participants. Participants will be approached by a RA who will explain the study to them. If consenting, participants will provide a verbal consent. All consent procedures will take place in the emergency department.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb>

For guidance, refer to the following Partners policy:

Informed Consent of Research Subjects:

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Informed-Consent-of-Research-Subjects.pdf>

#### DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

The PIs will be available at all times by telephone or email to receive complaints or concerns from participants or would-be participants. We will also be available at any time to discuss any questions, events or concerns from the RAs. The PI will be responsible for determining whether the research should be altered or stopped based upon any adverse events reported by participants or by concerns raised by the RA's. All the adverse events will be monitored by the PI and will be reported in accordance with PHSRC policies. We do not plan to utilize a DSMB.

This project was reviewed and approved by MGH Infection Control. Notice of approval by MGH Infection Control sent by Meredith Fay ([mfahy1@partners.org](mailto:mfahy1@partners.org)) on 12/2/2020.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

We will follow all standard Partners IRB procedures for monitoring and reporting adverse events.

## MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

We do not anticipate convening a DSMB for the study. The study PI and Co-I will conduct a data review with a random sample of the first 10 enrollees to determine that there are no issues with completion. All surveys will be monitored for completeness at the point of completion by study RAs. All discrepancies in data entry will be managed by the study PI and Co-I.

Prior to enrollment, all study RAs will be trained by the study PI/Co-I. We will conduct mock enrollments to ensure that RAs are adequately trained prior to enrollment of study participants.

We will continue to report all adverse events in compliance with PHRC reporting requirements.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/DSMP-in-Human-Subjects-Research.pdf>

Reporting Unanticipated Problems (including Adverse Events)

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Reporting-Unanticipated-Problems-including-Adverse-Events.pdf>

## PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

A confidential register of participants will be maintained on password protected device in order to ensure that already completed participants are not re-approached. This list will not be linked to responses nor will it be shared and it will be destroyed at the completion of the trial. In addition, data will be anonymized and analyzed as such after completion of the RedCap Surveys.

#### **SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS**

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Not applicable.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Not applicable.

#### **RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS**

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Not applicable.