IRB-HSR PROTOCOL

Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. That if this study involves any funding or resources from an outside source, or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
5. That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.
6. That all personnel working on this protocol will follow all IRB-HSR Policies and Procedures as stated on the IRB-HSR Website http://www.virginia.edu/vprgs/irb/ and on the School of Medicine Clinical Trials Office Website: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm
7. I will ensure that all those delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training, experience or credentialing to undertake those tasks.
8. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
9. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
10. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
11. That all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
12. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.
13. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
14. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.

15. That any serious deviation from the protocol will be reported promptly to the Board in writing.
16. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
17. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
18. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
19. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI is leaving UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
20. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
21. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept at least 6 years after completion of the study.
22. No data/specimens may be taken from UVa without a signed Material Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.
23. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Investigators Experience - (Redacted)

Signatures

Principal Investigator

_____	_____	_____
Principal Investigator Signature	Principal Investigator Name Printed	Date

The Principal Investigator signature is ONLY required if this is a new protocol, a 5 year update or a modification changing the Principal Investigator.

Department Chair

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

1. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
2. That the Principal Investigator is qualified to perform this study.
3. That the protocol is scientifically relevant and sound.

_____	_____	_____
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator.

Brief Summary/Abstract

The purpose of this randomized control trial is to compare visual performance and simulated driving performance of adults with astigmatism when wearing 1*DAY ACUVUE® MOIST for ASTIGMATISM (toric), 1*DAY ACUVUE® MOIST (spherical control), and 1*DAY ACUVUE® MOIST (placebo) contact lenses. Following informed consent, up to 79 adult subjects with nearsightedness and astigmatism will insert one of three types of soft contact lenses (placebo, spherical, or toric in randomized order). Each subject will then watch a video (15 minutes) for adaptation purposes, will read letters on standard eye charts, and will complete vision tests and driving tests in a driving simulator (45 minutes). The subject will repeat this sequence with the other two types of lenses. An ANOVA will be performed to look for a main effect of lens condition. Separate contrasts will be done to compare toric vs. spherical, toric vs. placebo, and spherical vs. placebo lenses. Investigating the lenses under these conditions, which involve eye movement demands, will lend insight into the potential advantages of toric over spherical contact lenses.

Background

1. Provide the scientific background, rationale and relevance of this project.

Problem: Driving is a routine part of daily living in industrialized nations, with over 211 million licensed drivers in the United States alone.[1] It is a complex skill that comes with a significant risk to safety. For example, in 2012 there were approximately 10.8 million documented vehicular collisions in the U.S, accounting for nearly 100 deaths daily.[2] In addition, vehicular collisions are expensive, costing the US economy over 276 billion dollars in 2012.[3] Given the prevalence of driving and the risks associated with it, safety is imperative.

Driving ability depends on adequately performing complex skills such as braking, steering, and controlling speed. These multi-dimensional skills require drivers to have good visual, biomechanical, and cognitive abilities, and the relative importance of these abilities to various aspects of driving performance is beginning to emerge.[4,5] The present study focuses on vision-

dependent abilities in order to evaluate a potentially overlooked effect of vision on driving performance: the consequences of driving with cylindrical blur from uncorrected astigmatism.

The effect of cylindrical blur on driving performance is of particular interest because there are a substantial number of people who drive with some degree of uncorrected astigmatism and potentially pose a risk to driving performance. This group comprises those who fail to update their prescriptions in a timely manner, those with residual astigmatism following lens or refractive surgeries, and contact lens patients with mild astigmatism (e.g. ≤ 0.75D) who are intentionally not corrected for astigmatism. These latter patients are often fitted with spherical contact lenses because the acuity loss from uncorrected astigmatism is small and a toric lens alternative can sometimes be unstable as well as more expensive than spherical lenses.[6,7] The number of patients with astigmatism who are wearing spherical contact lenses is shrinking with advances in toric contact lenses.[8,9] Nevertheless, the prescribing rates of toric contact lenses do not presently match the number of contact lens patients with astigmatism of 0.75D or more.[10] For people with mild astigmatism, it is usually assumed that there are few functional consequences of foregoing the cylindrical correction, but there is little data on which to base this assumption.

Evidence from studies of spherical blur suggests that cylindrical blur might negatively impact driving as well. Both spherical and cylindrical blur degrade some visual functions relevant to driving, such as high[7,11-20] and low[7,12,16,17] contrast acuity, reading speed[15,21,22] and subjective clarity.[11,12,15,23] With respect to driving, spherical blur has been weakly associated with reduced driving performance.[24,25,27,28] Increases in visual impairment with age, which include instances of uncorrected refractive error, are associated with increased crash rates.[29-31] This association might actually be stronger than it looks, since a portion of the effect is presumed to be masked by self-restriction of driving as blur increases with age.[31] If one can generalize from these similarities between cylindrical and spherical blur, then it might be expected that cylindrical blur would also reduce driving performance and perhaps safety.

To our knowledge, Wolffsohn[15] conducted the only other test to date of driving-relevant performance with cylindrical blur. In their study to discern the everyday challenges posed by uncorrected astigmatism in presbyopic individuals, 21 participants with up to 4.00 diopters of induced cylindrical blur performed several tasks including a split attention task in which they viewed a 14 inch computer monitor showing the perspective of a person sitting in a driver's seat. During a 90 second simulated drive, two hazards (a lead vehicle braking and an intrusion by a pedestrian) were presented 3 times each. Reaction times to the hazards were recorded, and the test was repeated 7 times. In this context, cylindrical blur had no effect on reaction time. The lack of an effect could be due to any number of factors, such as limitations imposed by using a small, 17 inch, graphically sparse computer monitor.[32] Therefore, the safety of astigmatic drivers using spherical-only corrections is still an open question.

Phase 1 and 2 Studies: To address this problem, a 3 phase plan was developed. The goal of the now completed Phase 1 and 2 studies was to determine if contact lens wearers with mild to moderate astigmatism (0.75 to 1.75D) are safer drivers when corrected with toric vs. spherical lenses. If significant differences were obtained in these first two Phases, then a Phase 3 Randomized Clinical Trial (RCT) was to be implemented to confirm the preliminary findings.

The Phase 1 and 2 studies showed that contact lens wearers with low to moderate astigmatism exhibited better simulated driving performance with toric lenses than with spherical lenses (Figure 1). Furthermore, post hoc analysis found that the greater the astigmatism correction, the greater the improvement in driving performance. These driving results suggest that correcting small amounts of astigmatism may be important to driving safety. Therefore, confirming these findings in a RCT will be important to the general public, insurance institutions, regulatory bodies, and contact lens companies alike.

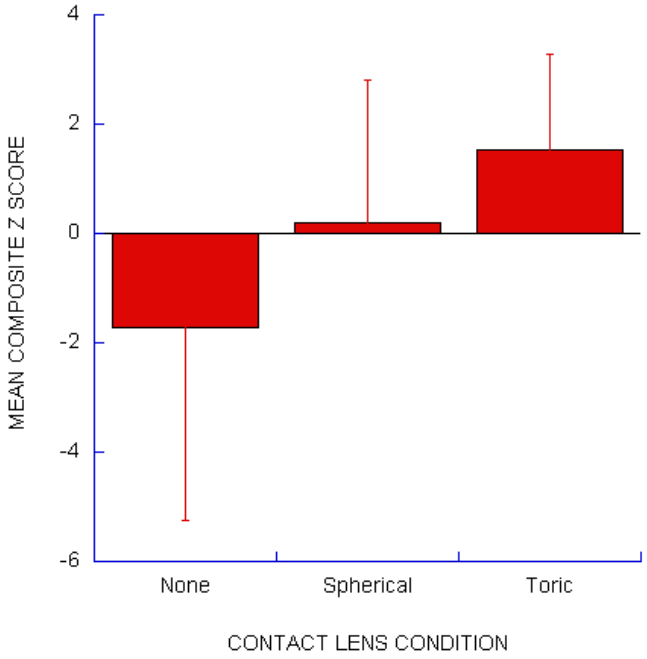

FIGURE 1: Mean Tactical Composite z scores for the 3 lens conditions in Phase 2. Note that the smallest error bars are found for the toric lens condition.

Following confirmation, it will be important to know the reasons why toric lenses improve driving performance. Is it simply due to visual acuity improvement or are other factors involved? In Phases 1 and 2, visual performance on a set of driving-relevant visual tests was used to investigate this question. Although visual performance was better with lens wear than without, differentiation between toric and spherical lens wear was not found using the methodology and technology employed. This outcome may indicate a lack of sensitivity in the driving-specific vision test battery we developed, or, in combination with the driving results it could instead suggest that there are unexplored visual factors at play in driving safety. One supposition is that the outcome could reflect eye movement demands. Driving involves large scale eye movements for scanning the environment, monitoring the roadway for hazards, and regularly checking instruments and mirrors. In contrast, standard vision tests primarily require fixations and small eye movement capabilities. We propose to investigate both of these

possibilities in Phase 3. Knowing the answers to these questions will lend insight into the specific advantages of toric over spherical contact lenses.

Hypotheses to be Tested

Consistent with our goal to replicate the Phase 2 outcomes, our primary hypothesis is:

H1: Drivers with low to moderate levels of astigmatism will drive more safely when wearing toric compared to spherical contact lenses.

Consistent with our goal to extend the Phase 2 findings, our secondary hypotheses are:

H2: Drivers with low levels of astigmatism will demonstrate better driving-specific visual abilities when wearing toric compared to spherical lenses.

H3: Any benefit in driving performance from wearing toric lenses (H1) will increase with the magnitude of astigmatism correction.

Following Phase 2 studies, new measures were added to the simulator, and refinements were made. Having made these improvements to the testing conditions, we also expect to demonstrate the following:

H4: Performance on driving-specific vision tests involving significant eye movements will be better with toric vs. spherical contact lens wear, while performance with toric and spherical corrections will be equivalent on tasks biased toward steady gaze.

H5: Subjects will be aware of better vision and better driving performance when driving with toric lenses.

H6: The driving-specific visual ability tests will correlate moderately with standard clinical vision tests. This will provide concurrent validation that driving-relevant vision tests offer advantages over standard visual tests when assessing drivers.

An additional study objective is to investigate whether toric contact lenses have any unique driving-specific benefits.

Study Design: Biomedical

1. Will controls be used?

Yes.

►IF YES, explain the kind of controls to be used.

1*DAY ACUVUE® MOIST contact lenses will be used as a control.

2. What is the study design?

The study design will consist of a double-blind (subjects and research assistant blind to hypotheses), randomized, cross-over design (toric vs. spherical vs. placebo contact lenses).

3. Does the study involve a placebo?

YES (1*DAY ACUVUE® MOIST contact lenses without corrective power)

►IF YES, provide a justification for the use of a placebo

The placebo will control for the effects of contact lens sensation and movement on vision and driving. All contact lenses in this study will be worn only in the test lab.

Human Participants

Ages: 18-39 years
Sex: Males and Females
Race: no restrictions

Subjects- see below

1. **Provide target # of subjects (at all sites) needed to complete protocol.**
   54 subjects

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.**
   We anticipate no more than 25 screen failures or dropouts.

3. **How many subjects will be enrolled at all sites?**
   79 subjects

4. **How many subjects will sign a consent form under this UVa protocol?**
   Up to 79 subjects

5. **Provide an estimated time line for the study.**

Months	1	2	3	4	5	6	7	8	9	10	11	12
Simulator upgrade												
IRB approval												
Subject recruitment												
Subject testing												
Data analysis/writing												

Inclusion/Exclusion Criteria

1. **List the criteria for inclusion**
   - Adult licensed driver

- Ages 18-39 years
- Corrected vision of 20/40 or better in each eye
- Astigmatism between 0.75 and 1.75 diopters in each eye
- Nearsightedness between 0 and -9 diopters in each eye
- No active eye infection
- No defective peripheral vision
- No bifocal correction
- Routinely wears toric contact lenses (more than 4 times per week)
- Routinely drives a car (more than 4 times per week)
- No history of motion, sea, or big screen (e.g. IMAX) sickness, and no persistent Simulation Adaptation Syndrome

2. List the criteria for exclusion

- Corrected vision worse than 20/40 in either eye
- No astigmatism in either eye
- Active eye infection
- Defective peripheral vision
- Wears bifocals
- Wears contact lenses less than 4 times per week
- Drives infrequently (less than 4 times per week)

3. List any restrictions on use of other drugs or treatments. None.

Statistical Considerations

1. Is stratification/randomization involved?

We propose using a cross-over design, because this will control for different degrees of refractive error, visual performance, and driving experience. Additionally, this will allow us to investigate "relative" and absolute benefits of toric contact lenses since subjects will serve as their own controls.

►IF YES, describe the stratification/ randomization scheme.

The study is a block design with lens type (placebo, sphere, toric) counterbalanced over 3 sessions of driving and vision testing during the study visit.

	Driving and vision testing		
# of subjects	Session 1	Session 2	Session 3
9	Placebo	Sphere	Toric
9	Placebo	Toric	Sphere
9	Sphere	Toric	Placebo
9	Sphere	Placebo	Toric
9	Toric	Placebo	Sphere
9	Toric	Sphere	Placebo

►**IF YES, who will generate the randomization scheme?**

__X___ Other: the PI

2. What are the statistical considerations for the protocol?

Primary Hypothesis:

Hypothesis 1: Drivers with low to moderate levels of astigmatism wearing toric rather than spherical lenses will demonstrate significantly safer driving simulator performance.

An ANOVA will be performed on the Composite Driving Scores to look for a main effect of lens condition (placebo lenses, spherical lenses, toric lenses). Separate contrasts will be done to compare toric vs. spherical, toric vs. placebo, and spherical vs. placebo lenses.

Secondary Hypotheses:

Hypothesis 2: Drivers with low to moderate levels of astigmatism wearing toric rather than spherical lenses will demonstrate significantly better driving-specific visual abilities.

An ANOVA will be performed on the Composite Vision Scores to look for a main effect of lens condition (placebo lenses, spherical lenses, toric lenses). Separate contrasts will be done to compare toric vs. spherical, toric vs. placebo, and spherical vs. placebo lenses.

Hypothesis 3: The driving performance benefit from toric lenses will be related to the degree of astigmatism in each subject.

Pierson correlations will be performed between subjects' composite driving scores and the magnitude of astigmatism correction in their toric study lenses.

Additional Hypotheses:

Hypothesis 4: Performance on driving-specific vision tests involving significant eye movements will be better with toric vs. spherical contact lens wear, while performance with toric and spherical corrections will be equivalent on tasks biased toward steady gaze.

An ANOVA will be performed on the scores from the Eye Movement test (operational driving test) to look for a main effect of lens condition (spherical vs. toric lenses).

Hypothesis 5: Subjects will be aware of better vision and better driving performance when driving with toric lenses.

We will run a Chi Square analysis comparing the subjective ratings from the Simulator Testing Record.

Hypothesis 6: Driving-specific vision tests will moderately correlate with standard vision tests.

Pierson correlations will be performed between subjects' performance on the standard clinical vision tests and the vision tests in the simulator for each contact lens condition. Acuity measures will be correlated with the operational static visual acuity test. Contrast sensitivity measures will be correlated with the operational contrast sensitivity and glare tests. The UFoV test will be correlated with the operational divided attention test.

Exploratory Analyses:

We will perform Multivariate MANOVAs on all of the driving and vision-based variables to determine if toric contact lenses have any unique driving-specific benefits.

3. Provide a justification for the sample size used in this protocol.

We will obtain consent from up to 79 potential subjects, in order to obtain data on 54 active drivers with astigmatism. Power analyses on Phase 2 outcome measures indicated a sample size of 43 would provide a >80% chance of finding a significant difference ($p<.05$) in driving performance between the spherical and toric lens conditions. This sample size also has enough power to show that driving performance with spherical and toric lenses would be superior to no-correction. This allows for up to 25 non-completers, consistent with our Phase 2 experience.

4. What is your plan for primary variable analysis?

The primary analysis evaluates differences between the contact lens conditions in regard to overall driving competency (primary outcome variable). Overall driving competency is defined by a composite score of 12 different response variables measured during a virtual drive comparable to a DMV on-road assessment. This will be done using a 3 Condition (placebo, sphere, toric) X 3 Session (1^{st}, 2^{nd}, 3^{rd} test) ANOVA, anticipating only a condition effect.

5. What is your plan for secondary variable analysis?

N/A

6. Have you been working with a statistician in designing this protocol?

Yes

IF YES, what is their name?

Karen Schmidt

7. Will data from multiple sites be combined during analysis?

NO

Biomedical Research

1. What will be done in this protocol?

Testing

Driving simulator: We will use the Model T^3 simulator, developed by us and initially used to assess and rehabilitate driving competence of military personnel following a traumatic brain injury.[i,ii] This simulator display covers a 210° field of view on a white curved screen inside an 8 foot diameter cylinder (Figure 1). The image is generated by three digital projectors, each projecting 70° segments of the visual image. While this system has side and rear view mirrors, these will be deactivated for this study. This system allows assessment of driving abilities at two levels: 1) operational or specific driving abilities like dynamic vision, and 2) tactical or general driving ability. Tactical driving ability will be assessed as drivers travel through simulated space to negotiate road and traffic demands on rural, urban, and highway roads.

Figure 1: The T^3 driving simulator

Operational Tests: These tests evaluate driving-relevant visual ability, using driving-relevant stimuli and context while driving through simulated space. For the operational tests, subjects will drive in the center lane of a three-lane highway, at a constant speed achieved through "cruise control". While at a constant speed, they will perform the six operational vision tests detailed below:

- Static visual acuity - reading aloud white letters on a black sign. The letters become progressively smaller.
- Contrast sensitivity - reading aloud letters that become progressively lighter on a white sign (lowering contrast).
- Visual processing speed - reading aloud pairs of letters on a black sign. The letters have progressively shorter exposure times.
- Dynamic vision - reading aloud letters that scroll across a black road sign at progressively faster rates.
- Glare sensitivity – this is the dynamic vision test in the presence of glare. Standard clinical instruments will be used to producing uniform glare.
- Eye movement test – reading aloud letters from road signs that appear briefly along the roadside. Subjects must make large eye movements and discern the letters quickly to be successful.

Tactical Test: The tactical driving test is a simulated drive through our standard road test scenarios (15 miles of rural, highway, or urban roads while negotiating various traffic signals,

traffic conditions and road conditions). The simulator keeps track of every driving response. This generates 17 different outcome variables (e.g. time spent exceeding the speed limit by 5 mph, number of excursions out of lane, and number of rolling stops).

Scoring: For both the operational and tactical tests, the separate outcome variables are converted to z-scores and then summed into a composite operational and tactical score. Performance under the three contact lens conditions will be compared on the composite scores (primary outcome variable) and on individual driving and vision parameters.

RCT procedure: This will be a randomized, double blind design, with testing under three contact lens conditions (toric, spherical, placebo). Each condition will be equally likely to occur first, and the order in which they are worn will remain unknown to the participants and research assistant. Neither the participants nor the research assistant will be told of the directional hypothesis, that the toric lenses will be superior to the spherical lenses.

Contact lenses will be ordered for potential subjects who pass the telephone screen, and delivered to the UVa Virginia Driving Safety Laboratory where they will be available on the potential subject's scheduled study testing day. Three sets of lenses (placebo, control, and test) will be ordered by Dr. Banton based on the individual's current contact lens prescription. These will be free of charge to the participants.

On the day of testing, participants will be instructed to come to the Virginia Driving Safety Laboratory wearing their usual contact lenses. After informed consent, the following will occur:

1. Subjects will be given a brief vision screening to verify that they meet the vision-based inclusion/exclusion criteria and to provide concurrent validation of the driving-relevant operational vision tests. The screening will include a brief ocular history, a review of their current contact lens prescription, a peripheral vision test in which subjects report when they see objects presented to their side, an inspection of the eyes with a small light for signs of irritation or infection, and clinical tests of visual ability (reading letters aloud from standard acuity charts, reading letters aloud from contrast sensitivity charts [with and without glare], and identifying visual targets in the Useful Field of View [UFoV] test). Participants will wear their personal contact lenses during these tests.
2. Participants will then undergo our Simulation Adaptation Screening (SAS) on the driving simulator. They will drive the simulator for 15 minutes to identify the occurrence of any simulation sickness (transitory nausea, upset stomach which diminishes upon termination of the simulated drive). If they rate simulation sickness greater than 1 on a 0 to 4 scale and it persists more than 5 minutes, they will be thanked, paid for 1 study hour, and excluded from further study participation.
3. We will dispense study contact lenses (placebo, spherical, or toric) to subjects in a double blinded manner (neither subject nor simulator staff will know the lens condition) according to the randomization scheme. Subjects will remove their personal contact lenses and insert the study lenses dispensed.

4. Participants will have 5 minutes of unstructured time to adapt to the study lenses.
5. Visual acuity, contrast sensitivity (with and without glare), and UFoV will be measured while the study lenses are being worn.
6. We will accompany the subject to the driving simulator.
7. Simulator testing will consist of a 45 minute period within which subjects will perform operational vision tests followed by the tactical driving test, both described above. A different simulated driving route will be used for each contact lens condition.
8. Subjects will rate their visual and driving performance in the simulator by completing the Simulator Testing Record.
9. Participants will remove and dispose of the study lenses.
10. Steps 3-9 will be repeated for the remaining contact lens conditions.
11. Upon study conclusion, subjects will sign a study compensation form. A check will be processed and mailed to the participant.

Procedure Summary: Overall, the test day will involve a four-hour fully counterbalanced block, where any one contact lens condition will be equally likely to occur during Session 1, 2 or 3. The study procedure overview is shown in Figure 2.

Figure 2: Procedure Overview and Timing

SCREENING	SESSION 1: LENS A	SESSION 2: LENS B	SESSION 3: LENS C
Informed Consent	Dispense lenses (5 min)	Dispense lenses (5 min)	Dispense lenses (5 min)
Vision screen (15 min)	Adaptation (5 min)	Adaptation (5 min)	Adaptation (5 min)
SAS screen (15 min)	Vision tests (10 min)	Vision tests (10 min)	Vision tests (10 min)
	Simulator (45 min)	Simulator (45 min)	Simulator (45 min)
	Questionnaire (5 min)	Questionnaire (5 min)	Questionnaire (5 min)
30 min	**70 min**	**70 min**	**70 min**

Data Collection: Tactical and operational data collected during simulator sessions will be saved directly to the simulator computer. Subjective ratings of driving performance and vision will be collected via the Simulator Testing Record (Simulator Testing Record.docx). Data collected outside of the simulator will be recorded on the Data Sheet (Acuvue Data Sheet.docx).

2. List the procedures, in bullet form, that will be done for <u>RESEARCH PURPOSES</u> as stipulated in this protocol.
ALL

3. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study?
No.

4. Will any of the procedures listed in item # 2 have the potential to identify an incidental finding? This includes ALL procedures, assessments and evaluations that are being done for <u>RESEARCH PURPOSES</u> that may or may not be considered investigational.

Yes.

__X___The examination(s) utilize(s) the same techniques, equipment, etc., that would be used if the subject were to have the examination(s) performed for clinical care. **There exists the potential for the discovery of clinically significant incidental findings.**

- The PI takes full responsibility for the identification of incidental findings:
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided to the subject with instructions to either show the letter to their PC or if the subject has no PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic. *For this study, if the vision screening indicates signs or symptoms of infection or irritation, the subject will be referred to their eye care professional.*

5. Do any of the procedures listed above, under question # 2, utilize any imaging procedures for <u>RESEARCH PURPOSES</u>?
No

6. Will you be using viable embryos?
No.

7. Will you be using embryonic stem cells?
No.

8. Are any aspects of the study kept secret from the participants?
Yes.

►**IF YES, describe:**
In each session, subjects will not be told which type of lens they are wearing (placebo, control, or test)

9. Is any deception used in the study?
No.

10. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.
The study contact lenses will be discarded at the end of each test session. At the end of the study, participants will immediately resume wearing their personal contact lenses.

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

1. Definitions

1.1 How will you define adverse events (AE)?

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

1.2 How will you define an unanticipated problem?

An unanticipated problem is any issue that involves increased risk(s) to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g serious loss of social status, loss of job, interpersonal conflict.)

1.3 What are the definitions of a protocol violation and/or noncompliance?

A protocol violation is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation**.** Protocol violations may be major or minor violations.

Noncompliance can be a protocol violation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulation**s.** Noncompliance may be serious or continuing

1.4 What is the definition of a data breach?

A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

2. What risks are expected due to the intervention in this protocol?

Expected Risks related to study participation	**Pick One**
There is a small risk that breaches of privacy and/or confidentiality might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol.	Occurs rarely
The risk of wearing study contact lenses is the same as wearing any contact lenses, e. g. corneal abrasion if put in improperly, eye infection if contaminated.	Occurs rarely
Simulation Adaptation Syndrome, characterized by: dizziness, nausea and/or headaches will be minimized because of the age group and the gradual introduction of virtual reality.	Occurs rarely

3. When will recording and reporting of unanticipated problems/adverse events begin?

__X___After subject signs consent

4. When will the recording/reporting of unanticipated problems/adverse events end?

__X___End of intervention

5. What is your plan for safety monitoring?

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Violation or Data Breach?

Type of Event	**To whom will it be reported:**	**Time Frame for Reporting**	**How reported?**
Unanticipated Problems tha are not adverse events or protocol violations This would include a Data Breach.	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Unanticipated Problem report form. *http://www.virginia.edu/vprgs/irb/HSR_docs/Forms/Reporting_*

			Requirements-Unanticipated_Problems.doc)
Protocol Violations/Noncompliance (*The IRB-HSR only requires that MAJOR violation be reported, unless otherwise required by your sponsor, if applicable.)* **OR** **Enrollment Exceptions**	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Violation, Noncompliance and Enrollment Exception Reporting Form *http://www.virginia.edu/vprgs/irb/hsr_forms.html* *Go to 3rd bullet from the bottom.*
Data Breach of Protected Health Information	The UVa Corporate Compliance and Privacy Office ITC: if breach involves electronic data Police if breach includes items that are stolen: Stolen on UVA Grounds OR Stolen off UVa Grounds- contact police department of jurisdiction of last known location of PHI	As soon as possible and no later than 24 hours from the time the incident is identified. As soon as possible and no later than 24 hours from the time the incident is identified. IMMEDIATELY.	UVa Corporate Compliance and Privacy Office- Phone 924-9741 **ITC:** Information Security Incident Reporting procedure, http://www.itc.virginia.edu/security/reporting.html Police: phone- (434) 924-7166

Payment

1. **Are subjects being reimbursed for travel expenses** (receipts /mileage required)**?**
   No.

2. **Are subjects compensated for being in this study?**
   Yes.

2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?
$120

2b. Explain compensation to be given.
Subjects can earn up to $120 ($30 per test completed, for the vision screening and each of the 3 driving sessions).

2c. Is payment pro-rated?
YES – subjects will earn $30 per test completed, for the vision screening and each of the 3 driving sessions

2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?
Yes.

2d(i). How will the researcher compensate the subjects?
__X___ Check issued to participant via UVA Oracle or State system

2d(ii). Which category/ categories best describes the process of compensation?
__X___ All compensation will be made via check issued to participant via UVA Oracle or State system

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?
There are no immediate benefits for subjects participating in this study;
Potential benefits to society include increased knowledge regarding the efficacy of toric lenses for people with astigmatism, with regard to driving.

2. Do the anticipated benefits justify asking subjects to undertake the risks?
There is minimal risk to subjects – the risks of inserting contacting lenses are no greater than those encountered by these individuals in their daily lives. Simulator assessment poses a minimal risk of Simulation Adaptation Syndrome (characteristics listed above), the symptoms of which are transient. The risk benefit ratio is acceptable.

Bibliography

Cox DJ, Banton T, Record S, Grabman JH, Hawkins RJ. (2015). Does correcting astigmatism with toric lenses improve driving performance? *Optometry and Vision Science*, 92(4), 404-411.

Cox, DJ, Davis, M, Singh, H, Barber, B, Nidiffer, FD, Trudel, T, Mourant, R, & Moncrief, R. (2010). Driving Rehabilitation for Military Personnel Recovering from Traumatic Brain Injury using Virtual Reality Driving Simulation: A Feasibility Study. *Military Medicine, 175,* 411-6.

Cox, CV, Moncrief, R, Wharam, R, Mourant, R, & Cox, DJ. (2009). Does virtual reality driving simulation training transfer to on-road driving in novice drivers? A pilot study. *Chronicle for Driver Education Professionals,* 57, (1) 9-22.

APPENDIX: Legal/Regulatory

Recruitment

The following procedures will be followed:

- Finders fees will not be paid to an individual as they are not allowed by UVa Policy.
- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
- No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

Compensation in Case of Injury

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/2439847) the UVa Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVa Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records
- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

Subject Complaints

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/243-9847), the UVa Health System Patient Relations Department (924-8315).

Request for Research Records from Search Warrant or Subpoena

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVa Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

APPENDIX: FDA Verification of Approval

1. What is the name of the approved drug, device or biologic?

1*DAY ACUVUE® MOIST (spherical control and placebo) and 1*DAY ACUVUE® MOIST for ASTIGMATISM (toric) contact lenses.

2. What document have you provided to confirm FDA approval?

The website for package insert is:
http://www.acuvue.com/sites/default/files/content/us/pdf/M-09-14-00%201DAVM%20PI-FIG%20%28website%29.pdf#zoom=100

3. Is the study required by the FDA?

No.

4. Is the study initiated by an investigator and not a commercial company?

Yes.

5. Is the study retrospective?

No.

6. Does the study involve research on a drug/ device in an already approved population/ condition?

Yes

7. Does the study involve research only on a drug and NOT on a device?

No.

APPENDIX: Device Information: (Device being evaluated)

1. **List name of device being evaluated**.

1*DAY ACUVUE® MOIST (spherical control and placebo) and 1*DAY ACUVUE® MOIST for ASTIGMATISM (toric) contact lenses.

2. **Describe pertinent animal data that is available regarding the safety of this device**.

N/A, this is a marketed device.

3. **Describe pertinent human data that is available regarding the safety of this device**.

See package insert: http://www.acuvue.com/sites/default/files/content/us/pdf/M-09-14-00%201DAVM%20PI-FIG%20%28website%29.pdf#zoom=100

4. **Have there been any human deaths associated with this device?**
   No.

5. **In how many humans has this device been used previously?**
   This is a marketed device, so it has been used in thousands of individuals.

6. **If this protocol will be used in children describe any previous use of this device with children of a similar age range**.
   N/A

7. **Is this device implanted?**
   No,

8. **Is this a post-marketing study?**
   No.

9. **Does this device have an IDE# from the FDA?**
   No, it is a marketed device.

►IF NO, check the applicable items in the table below:

IDE Exemption Criteria

X	A legally marketed device when used in accordance with its labeling
	A diagnostic device if it complies with the labeling requirements in §809.10(c) and if the testing: • is noninvasive; • does not require an invasive sampling procedure that presents significant risk; • does not by design or intention introduce energy into a subject; and • is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure; *Additional guidance for an in vitro diagnostic device studies can be found in "Regulating In Vitro Diagnostic Device (IVD) Studies."* http://www.fda.gov/cdrh/comp/ivdreg.html
X	Consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) [that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)] AND if the testing is not for the

	purpose of determining safety or effectiveness and does not put subjects at risk;
	A device intended solely for veterinary use;
	A device shipped solely for research with laboratory animals and contains the labeling "CAUTION – Device for investigational use in laboratory animals or other tests that do not involve human subjects."
	A custom device : According to 21CFR812.2(c) (7) a custom device as defined in 812.3(b) is exempt unless the device is being used to determine safety or effectiveness for commercial distribution. A custom device means a device that: (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist; (2) Is not generally available to, or generally used by, other physicians or dentists; (3) Is not generally available in finished form for purchase or for dispensing upon prescription; (4) Is not offered for commercial distribution through labeling or advertising; and (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.
	NA- None of the items above apply- device determined to NOT be exempt from IDE regulations. *If applicable will submit any documentation from the sponsor regarding device risk determination (eg. significant risk vs. non-significant risk)*

APPENDIX: Unapproved Device Use
(Unapproved Device being used but not evaluated)

1. **List name of device(s) being used in an unapproved manner in this protocol**.
   Model T3 Driving Simulator, from MBFARR, LLC (General Simulation).

2. **Do you confirm the device is only being USED and NOT being evaluated in this study?**
   YES

3. **Is the device a Research Use Only (RUO) device?**
   NO – it is a commercially available driver training and assessment system.

   ►If the device is NOT a RUO device, is the device currently approved for any indication?
   No

4. **In how many humans has this device been used previously as it is being used in this study?**
   654 non-research subjects for driving evaluations and 108 research subjects.

5. **Describe pertinent human data that is available regarding the safety of this device as you are using it in this protocol.**
   Five research studies (total of 108 subjects) have been conducted using the device and there were no instances of complications other than 5 cases of simulator sickness. 4 of these were among senior drivers and 1 involved a younger person undergoing chemotherapy. The simulation sickness spontaneously resolved when the simulator drive was stopped. The simulator is being upgraded with new computers and projectors prior to beginning the proposed study in order to make the images clearer and the movement smoother, thus reducing the possibility of simulation sickness.

6. **If this protocol will be used in children, describe any previous use of this device with children of a similar age range as it is being used in this study.**
   The device will not be used by children.

7. **What steps will be taken to minimize risk?**
   A screening for Simulation Adaptation Syndrome will be conducted to rule out participants who may not be able to tolerate driving the simulator without feeling discomfort.

8. Would you consider the use of this device to be minimal risk? Why or why not?
The device is of minimal risk. The only risk we know of is that some people can feel uncomfortable after driving the simulator for a while. This response is similar to the discomfort some people feel from watching large-screen movies. The response is transient, is less likely to occur in younger adults (our population target), and does not affect everyone. Screening is designed to exclude those who are susceptible to this risk.

APPENDIX: Recruitment

1. How do you plan to <u>identify</u> potential subjects?

a.____ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or an Improvement Project.

b____ Review of a database that was established to keep data to be used for future research such as the CDR, departmental research database or use of data from a separate current active research protocol.

c. ____ Patient's UVa health care provider supplies the UVa study team with the patients contact information without patients' knowledge.

d. __X__ Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating. (Health care provider may or may not also be the a member of the study team)

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.

2. How will potential subjects be <u>contacted?</u>

a.____Direct contact of potential subjects by the study team via letter, phone, direct e-mail. Members of study team ARE NOT health care providers of patients. Information will not be collected from psychotherapy notes.

b.____Potential subjects will be approached while at UVa Hospital or Health Clinic by a person who is NOT a member of their health care team. Information will not be collected from psychotherapy notes.

c.____Direct contact of potential subjects by the study team by approaching in person at UVa or via letter, phone, direct e-mail. Members of study team contacting potential subjects ARE health care providers of patients.

d._X___ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.)

3. **Will any additional information be obtained from a potential subject during "prescreening"?** Yes, potential subjects will be asked to provide their current contact lens prescription so that the study lenses may be ordered prior to their study visit.

IF YES, Will any of the questions involve health information?
Yes

IF YES, will you collect HIPAA identifiers with the health information?
Yes.

IF YES, which HIPAA identifiers will be recorded?
Name, telephone number, and e-mail address will be recorded.

Do you confirm that health information with HIPAA identifiers will not be shared outside of UVa until a consent form is signed or only shared in a de-identified manner?
Yes

4. **Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?** No

5. **How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor (if applicable)?**

   Individuals who respond to study advertisements and who appear to meet the study inclusion/exclusion criteria in a phone interview will be scheduled to come to the Virginia Driving Safety Lab for consent and subsequent testing. Individuals will be met by a study team member in a private, quiet room to recheck their study eligibility, review all aspects of the study reflected in the consent form, and insure that all questions are addressed. Once the individual is fully informed, written consent will be obtained. Study subjects will be given a copy of the signed consent form.

6. **Will subjects sign a consent form for any part of the study?**
   Yes.

7. Will the study procedures be started the same day the subject is recruited for the study?

Yes, for subject convenience they may plan to continue with the study visit the same day that consent is signed.

►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.
The subject may take as much time as desired to make a decision. Scheduling the study visit along with the consent process may be done for subject convenience; however, subjects may plan a separate consent visit if desired.

►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.
Questions will be encouraged and answered. Subjects may choose to take the consent form home with them and postpone a decision.

8. Is there the potential to recruit economically or educationally disadvantaged subjects, or other vulnerable subjects such as students or employees?

Yes.

IF YES, what protections are in place to protect the rights and welfare of these subjects so that any possible coercion or undue influence is eliminated?

Recruitment is indirect to minimize coercion. Members of the research team are not teaching or grading students, so there will not be student-teacher pressure to participate. Undue influence is unlikely, as compensation is reasonable. The fact that study participation is completely voluntary is written in the consent form and will be reiterated verbally to potential subjects.

9. Do you need to perform a "dry run" of any procedure outlined in this protocol?

No.

Privacy Plan

The following procedures must be followed.

- The data will be secured per the Data Security Plan of this protocol.
- Only investigators for this study and clinicians caring for the patient will have access to data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about *The Importance of Choosing Strong Passwords.*
- Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.

  If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.
- UVa University Data Protection Standards will be followed http://www.virginia.edu/informationsecurity/dataprotection.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "Electronic Storage of Highly Sensitive Data Policy". Additional requirements may be found in the University's Requirements for Securing Electronic Devices.
- If identifiable data is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- Data will be securely removed from the server/drive, additional computer(s), and electronic media according to the University's Electronic Data Removal Policy.
- Data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Policy.
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and University Data Protection Standards .
- Data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.
- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

Summary of Requirements to Comply with UVa Health System, Medical Center and University Policies and Guidance as noted above:

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
General Issues	*General Issues*
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See Encryption Solutions Guidance *Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.*	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security server/drives managed by Information Technology Services or the “F” and “O” managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN	
Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with ISPRO or Health System Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ Health System: Web Development Center:	
Individual-Use Device	*Individual-Use Device*
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with ISPRO or Health System Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ Health System: Web Development Center:	
Individual-Use Device	*Individual-Use Device*
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with ISPRO or Health System Web Development Office: 434-243-6702 University Side: IT-Security@virginia.edu Health System: Web Development Center: Contract must include required security measures.	
LOST OR STOLEN:	*LOST OR STOLEN:*
UVaCollab, QuestionPro. May also NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	QuestionPro. May NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.
LOST OR STOLEN:	*LOST OR STOLEN:*
Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy. Any data breach will also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem.	Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy. Any data breach will also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem.

** Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*
***The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison's), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.*

[i] Cox CV, Moncrief R, Wharam R, Mourant R, Cox DJ. (2009) Does virtual reality driving simulation training transfer to on-road driving in novice drivers? A pilot study. *Chronicle for Driver Education Professionals,* 57 (1), 9-22.
[ii] Cox DJ, Davis M, Singh H, Barber B, Nidiffer FD, Trudel T, Mourant R, Moncrief R. (In Press) Driving Rehabilitation for Military Personnel Recovering from Traumatic Brain Injury using Virtual Reality Driving Simulation: A Feasibility Study, *Military Medicine*.