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

Dr. Kesser is an associate professor in the division of otology/neurotology within the department of Otolaryngology – Head and Neck Surgery. He has over fifteen years of experience functioning clinically and as an investigator. He has numerous publications in the field of otology including chronic ear disease, the subject of this study. He has ample clinical experience with the long term medical and surgical management of these patients.

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

In theory, patients with Eustachian tube dysfunction as defined by negative pressure on tympanometry will have more resistance in the Eustachian tube. Thus, the pressure required to open should higher than the pressure in patients with normal function. This relationship has never been evaluated. It would have an impact not only when considering CPAP as a treatment modality, but also when considering CPAP in post-operative patients undergoing otologic surgery. We hypothesize an inverse relationship between middle ear pressure and air pressure as delivered by CPAP required to create both subjective ("popping" the ears) and objective (tympanometric and otoscopic) increase in middle ear pressure. We will begin recruiting participants from clinic and the general population. Each individual participant will be assigned a participant ID. The participant will be brought to the exam room and fitted with a new CPAP mask. Photodocumentation of otoscopic examination will be obtained for baseline as well as tympanometric measurement. Starting at a set pressure, the patient will be given a set number of breaths. Then, the setting will be increased until a maximum tolerable pressure is reached (no higher than 20 cm H_2O). The participant will be asked to notify the examiner when he or she has a sensation of his ears "popping", and that level will be documented. Photodocumentation and tympanometric measurement will be obtained. These will be used to plot correlation between opening pressure and both initial middle ear pressure as observed on tympanometry and otoscopic evlauations. The Sade classification scheme will be used to grade otoscopic findings. These findings will be analyzed using SPSS and tests include Spearman correlations, t-tests, and Wilcoxon Rank-Sum Test.

Background

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

Eustachian tube dysfunction and chronic otitis media

Eustachian tube dysfunction is a poorly defined and understood clinical entity. While it is agreed upon that it is the primary etiology of chronic otitis media, particularly in adults, the exact physiology has been elusive. While many different theories have been proposed with evidence presented in addition, *Cummings* (Flint, *et al.*) describes two key physiological changes, whether it be mechanical obstruction (e.g., adenoid hypertrophy) or functional (normal anatomy with poor function). The former is likely more common in children with the latter best described in patients with cleft palate. Purely anatomical comparisons have not provided a definite etiology for why some individuals have significantly greater dysfunction.

In describing the clinical entity of Eustachian tube dysfunction, the literature varies between symptom descriptions, objective findings, and clinical outcomes (ie, need for surgery, etc.). Even when using objective findings, there is disagreement as to what degree of negative pressure on tympanometry constitutes Eustachian tube dysfunction. Attempts to measure function have been unsuccessful. A recent review by Norman, *et al*. found such significant variation in how ETD was defined in the literature that it was felt that no reasonable conclusions could be drawn regarding specific, consistent diagnostic criteria. While multiple symptom score indices have been proposed, including the Eustachian tube dysfunction questionnaire (ETDQ-7, Figure 1), they have not reached widespread use.

Figure 1. The Seven Item Eustachian Tube Dysfunction Questionnaire (ETDQ-7).

Over the past 1 month, how much has each of the following been a problem for you?	No Problem			Moderate Problem			Severe Problem
1. Pressure in the ears?	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Crackling or popping sounds in the ears?	1	2	3	4	5	6	7
6. Ringing in the ears?	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled?	1	2	3	4	5	6	7

Treatment of ETD has also been elusive. While many methods have been proposed, including but not limited to devices such as the Otovent (Kestrel Medical, United Kingdom), surgical interventions such as balloon dilation, myringotomy with ventilation tube placement, laser coagulation, and others, none has provided sufficient data to prove a long-term benefit of the stated intervention. The value of preventing progression of chronic otitis media and its sequelae – including cholesteatoma, hearing loss, severe infections, and need for repeated surgical interventions – is unquestioned.

Continuous positive air pressure therapy

Continuous positive air pressure therapy (CPAP) is a highly successful treatment of an increasingly common problem – obstructive sleep apnea (OSA). Patients using CPAP for OSA have been evaluated in regard to middle ear function. Common otologic complaints related to CPAP include aural fullness and the development of serous otitis media. On the whole, CPAP use is quite safe for the middle ear, although rare case reports have suggested association with negative side effects including a single report of perilymph fistula formation. The most likely mechanism by which the ears are affected by CPAP is that air is forced into the Eustachian tube. Multiple studies have found higher middle ear pressures with CPAP use, although in patients without ETD, the middle ear pressure is likely to revert to a normal pressure. The impact of CPAP on the middle ear still has significant room for investigation.

Hypothesis to be Tested

There is a specific CPAP pressure at which individuals' Eustachian tubes will allow air to be transmitted to middle ear. We will be able to correlate this to initial middle ear pressure.
Primary outcome measure: CPAP pressure required for middle ear insufflation.
Secondary outcome measures:

- Change in middle ear pressure with CPAP use
- Otoscopic findings
- Patient symptom survey (ETDQ-7)

Study Design: Biomedical

1. **Will controls be used?**No
2. **What is the study design?** Cohort study
3. **Does the study involve a placebo?**No

Human Participants

Ages: 18-99
Sex: **M or F**
Race: **Any**

Subjects- see below

1. **Provide target # of subjects (at all sites) needed to complete protocol.** 29
2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.** 5%
3. **How many subjects will be enrolled at all sites?** 31
4. **How many subjects will sign a consent form under this UVa protocol?** 31
5. **Provide an estimated time line for the study.**

After IRB approval, we anticipate completion of enrollment and study completion within 2 months. Data analysis will be concluded within 6 months of study initiation. No follow up is required.

Inclusion/Exclusion Criteria

1. **List the criteria for inclusion**
   - Age ≥18
   - No use of CPAP within past 30 days
   - Individuals presenting to the UVA otolaryngology clinic who are otherwise healthy

2. **List the criteria for exclusion**
   - Pre-existing cardiopulmonary disease that presents a risk with CPAP use
   - Inability to tolerate CPAP
   - Recent otologic surgery

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

Statistical Considerations

1. **Is stratification/randomization involved?**

As there will be no comparison group, there will not be stratification or randomization. Any grouping will be performed in the data analysis portion based on data acquired within the study.

2. **What are the statistical considerations for the protocol?**

Primary endpoint:

- CPAP pressure at which a significant change in middle ear pressure occurs

Secondary endpoints:

- Tympanometry
- Otoscopy
- ETDQ-7

3. Provide a justification for the sample size used in this protocol.
We anticipate accruing 5-10 participants per week. The accrual goal will be 32, with an interim analysis at 16. We anticipate a very low dropout rate, but will account for a 5% rate. Based on calculations assuming a -0.500 correlation between "opening pressure" (CPAP pressure) and starting middle ear pressure, 29 participants are needed to show statistically significant differences. There is no required follow up, so this provides minimal drop-out risk.

4. What is your plan for primary variable analysis?
We will perform Spearman correlation calculations to estimate the relationship of CPAP pressure at which the ears "pop" to the initial and final tympanometric pressure as well as the change in tympanometric pressure.
5. What is your plan for secondary variable analysis?
We will use t-tests and/or ANOVA to assess the relationship of the above pressures to ETDQ-7 responses as well as using ROC curve analyses to determine if there is a true tympanometric pressure cut point to define ETD.
6. Have you been working with a statistician in designing this protocol?No

7. Will data from multiple sites be combined during analysis? No

Biomedical Research

1. What will be done in this protocol?

- Each individual participant will be assigned a participant ID.
- The participant will be brought to the exam room and fitted with a new CPAP mask.
- Photo-documentation of otoscopic examination will be obtained for baseline as well as tympanometric measurement.
- Starting at a set pressure, the patient will be given a set number of breaths. Then, the setting will be increased until the maximum tolerable pressure or a maximum pressure of 20 cm H2O has been reached.
- The patient will be asked to notify the examiner when he or she has a sensation of his ears "popping", and that level will be documented.
- Photo-documentation and tympanometric measurement will be obtained.

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

- Tympanometry
- Otoscopy
- Short term use of CPAP (10 minutes)
- ETDQ-7 for our research purposes.

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 RESEARCH PURPOSES that may or may not be considered investigational. yes

__x__This examination(s) utilizes non-standard/investigational, technique, equipment, etc. It is impossible to determine the significance of such results, therefore abnormalities will not be shared with the subject because the meaning of the exam is not yet proven and is of unknown clinical benefit.

5. Do any of the procedures listed above, under question # 2, utilize any imaging procedures for RESEARCH PURPOSES? 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?** No
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.** NA

11. Will your study involve measures (C-SSRS/BID/SCID etc.) used to assess for depression and/or suicidality for research purposes? No

Taping/Photography

1. Will participants be recorded on audiotape? No

2. Will participants be photographed or recorded on videotape? Yes

►IF YES, answer the following questions.

2a. Will their faces be shown?No

2b. What steps will be taken to protect the privacy of the subjects?

The device used to take the photographs (iPhone) will be secured per UVA protocol and only used for research purposes. The images will only be tied to a participant ID. The images will only be of the ear drum and as such will not allow for identification if seen.

2c. What data will be captured from the photo or videotape that could not be obtained in other ways? Image of the tympanic membrane (ear drum). This cannot otherwise be reviewed in a blinded fashion.

2d. How is this data critical to this research?

This provides an additional clinical measurement that allows for analysis of patients.

2e. When will data from the tapes be transcribed?

Within one month of obtaining them they will be transferred to a secure file and deleted from the portable device.

2f. When will the tapes be destroyed?At the conclusion of the study.

2g. Will participants be photographed, recorded or videotaped without their knowledge? No

3. If a subject withdraws from the study how will you withdraw them from the audiotape, videotape or photograph? Delete the files.

Data and Safety Monitoring Plan

1. Definition:

1.1 How will you define <u>adverse events</u> (AE)) for this study?

__x___An adverse event will be considered any undesirable sign, symptom or medical or psychological condition **even if the event is not considered to be related** to the investigational drug/device/intervention. Medical condition/diseases present before starting the investigational drug/intervention will be considered adverse events only if they worsen after starting study treatment/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. Adverse events also include any problems associated with the use of an investigational device that adversely affects the rights, safety or welfare of subject s.

1.2 How will you define <u>serious adverse events</u>?

__x___A serious adverse event will be considered any undesirable sign, symptom, or medical condition which is fatal, is life-threatening, requires or prolongs inpatient hospitalization, results in persistent or significant disability/incapacity, constitutes a congenital anomaly or birth defect, is medically significant and which the investigator regards as serious based on appropriate medical judgment. An important medical event is any AE that may not result in death, be life-threatening, or require hospitalization but may be considered an SAE when, based upon appropriate medical judgment, it may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in the definitions of SAEs.

1.3 What is the definition of an <u>unanticipated problem?</u>

Do not change this answer

An unanticipated problem is any event, experience that meets ALL 3 criteria below:

- Is unexpected in terms of nature, severity or frequency given the research procedures that are described in the protocol-related documents AND in the characteristics of the subject population being studies
- Related or possibly related to participation in research. This means that there is a reasonable possibility that the incident may have been caused by the procedures involved in the research study.

- The incident suggests that the research placed the subject or others at greater risk of harm than was previously known or recognized OR results in actual harm to the subject or others

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

Do not change this answer

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.

Additional Information: see the IRB-HSR website at http://www.virginia.edu/vpr/irb/HSR_docs/Forms/Protocol_Violations_%20Enrollment_Exceptions_Instructions.doc

1.5 If pregnancy occurs how will this information be managed?

___x__ Other Study enrollment and completion will occur in the same encounter, so it is not possible for the pregnancy status to change during the study.

1.6 What is the definition of a Protocol Enrollment Exception?

___x__NA- No outside sponsor

1.7 What is the definition of a data breach?

Do not change this answer

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.

Additional Information may be found on the IRB-HSR Website: Data Breach

2. Identified risks and plans to minimize risk

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

Expected Risks related to study participation.	**Frequency**
• Runny Nose • Skin irritation • Dry mouth • Swallowing air • Nasal congestion, epistaxis • Abdominal discomfort	____Occurs frequently __x__Occurs infrequently ____Occurs rarely ____Frequency unknown
• Dizziness	____Occurs frequently

• Trouble breathing	____Occurs infrequently __x__Occurs rarely ____Frequency unknown
Violation of subject's privacy and confidentiality	Minimized due to the requirements of the privacy plan in this protocol

The common risks of CPAP are mouth dryness, rhinorrhea, nasal congestion, and aerophagia, which are all mild. Rare risks of moderate to severe complications include epistaxis, otologic complaints, dizziness, and trouble breathing.

2.2 List by bullet format a summary of safety tests/procedures/observations to be performed that will minimize risks to participants: N/A

2.3 Under what criteria would an INDIVIDUAL SUBJECT'S study treatment or study participation be stopped or modified

___x__At subject, PI or sponsor's request

___x__Treatment would be stopped if the subject had a serious adverse event deemed related to study, or study drug will be increased if the subject tolerates dosing

2.4 Under what criteria would THE ENTIRE STUDY need to be stopped.

___x__Per IRB, PI

2.5 What are the criteria for breaking the blind/mask?

___x__Other:: If an otoscopic finding were identified that was not noted on clinical exam.

2.6 **How will subject withdrawals/dropouts be reported to the IRB prior to study completion?**

__x___IRB-HSR continuation status form

3. Adverse Event / Unanticipated Problem Recording and Reporting

3.1 Will all adverse events, as defined in section 1.1, be collected/recorded? No

►IF NO, what criteria will be used?

_x____Only adverse events that are deemed related AND serious

3.2 How will adverse event data be collected/recorded?

___x__Spreadsheet: paper or electronic

3.3. How will AEs be classified/graded?

___x__World Health Organization Criteria (WHO)

_X_ Serious/Not serious

3.4 What scale will the PI use when evaluating the relatedness of adverse events to the study participation?

__x___The PI will determine the relationship of adverse events to the study using the following scale:

Related:	AE is clearly related to the intervention
Possibly related:	AE may be related to the intervention
Unrelated:	AE is clearly not related to intervention

3.5 When will recording/reporting of adverse events/unanticipated problems begin?

___x__After subject begins study drug/ device placement/intervention /study-related procedure/specimen collection

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

__x___ Subject completes intervention and follow up period of protocol

3.7 How will Adverse Events, Unanticipated Problems, Protocol Violations and Data Breaches be reported? Complete the table below to answer this question

Type of Event	To whom will it be reported:	Time Frame for Reporting	How reported?
Any internal event resulting in death that is deemed DEFINITELY related to (caused by) study participation *An internal event is one that occurs in a subject enrolled in a UVa protocol*	IRB-HSR	Within 24 hours	IRB Online and phone call www.irb.virginia.edu/
Internal, Serious, Related, Unexpected adverse event	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event. *Timeline includes submission of signed hardcopy of AE form.*	IRB Online www.irb.virginia.edu/
For Device Studies: Unanticipated adverse device effects (internal)	IRB-HSR	Within 10 calendar days of the study team receiving knowledge of the event	IRB Online www.irb.virginia.edu/
Unanticipated Problems that are not adverse events or	IRB-HSR	Within 7 calendar days from the	Unanticipated Problem report form.

protocol violations This would include a Data Breach.		time the study team received knowledge of the event.	*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** *See definition- only allowed if there is a commercial sponsor or a DSMB that has granted the enrollment exception.*	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	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 UVa Police-Phone- (434) 924-7166

4. **How will the endpoint data be collected/recorded.**

___x__Protocol specific case report forms

5. Data and Safety Oversight Responsibility

5.1. Who is responsible for overseeing safety data for this study?

___x__No additional oversight body other than PI at UVa

5.2. What is the composition of the reviewing body and how is it affiliated with the sponsor? n/a

5.3. What items will be included in the aggregate review conducted by the PI?

___x__All adverse events

_____Unanticipated Problems

_____Protocol violations/Issues of noncompliance

_____Audit results

_____Application of dose finding escalation/de-escalation rules

_____Application of study designed stopping/decision rules

_____Early withdrawals

_____Whether the study accrual pattern warrants continuation/action

_____Endpoint data

5.4 **How often will aggregate review occur?**

For additional information on aggregate review see:
www.virginia.edu/vpr/irb/hsr/continuations.html#aggreview

_____NA- PI is not the overall person overseeing the safety data for this study.

_____Per Enrollment/Events

__x___Annually

5.5. How often will a report, regarding the outcome of the review by the DSMB/DSMC, be sent to the UVa PI? n/a

5.6. How will a report of the information discussed in question 5.4 OR 5.5 be submitted to the IRB?

__x___Part of IRB-HSR continuation status form

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?

We do not anticipate any direct benefits to the patient in this study. We anticipate a benefit to society in that we will have a better understanding of the amount of CPAP pressure required to affect the middle ear. This may allow for use as treatment (for patients with ETD) and/or for advisory data in post-operative patients after ear surgery.

2. Do the anticipated benefits justify asking subjects to undertake the risks?
The risks of this procedure are seen as very low. The subjects will be screened for any comorbid cardiopulmonary disease that may increase the risk of adverse events with CPAP use.

Bibliography

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APPENDIX: Support Source

1. Describe what will be provided and by whom.

ResMed:

- 1 CPAP machine
- 50 masks

2. Do you confirm that you will obtain a contract/ material transfer agreement with the provider via the Medical Center Procurement office or Office of Sponsored Programs (OSP) ospnoa@virginia.edu**?**

Yes

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

INSTRUCTIONS: This section is to provide the IRB with information about the safety of a device that is being USED, but not evaluated in this study for safety and efficacy. The device may have FDA approval and is being used for a non-approved indication OR the device may not have FDA approval [these are typically known as Research Use Only (RUO) Devices]. Again the RUO Device is only being USED and NOT being evaluated for safety and efficacy in this study. The information below will be used by the IRB to make a minimal risk determination regarding this protocol.

1. **List name of device(s) being used in an unapproved manner in this protocol**.
   ResMed AirSense 10 CPAP machine

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

   ►**If the device is NOT a RUO device, is the device currently approved for any indication?** Yes

   ►**If the device is currently approved list the indication:**
   Obstructive sleep apnea

   ►**If the device is currently approved, do you confirm that results will not be used in clinical care of the subject (e.g. will not be used for diagnosis or treatment?)** Yes

4. **In how many humans has this device been used previously as it is being used in this study?** 0

5. **Describe pertinent human data that is available regarding the safety of this device as you are using it in this protocol.**
   Other CPAP devices have been used in multiple other studies of patients with Eustachian tube dysfunction, with a total of 84 patients among three studies (Akbulut, et al, Yung, Lin, et al). The only side effects experienced were minor and included mild claustrophobia and otalgia. The duration of use for this study is shorter than has previously been studied (in sleep apnea).

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.** NA

7. **What steps will be taken to minimize risk?**
   The short term, monitored nature of this study will allow a patient to immediately cease use if they have any discomfort or other intolerance.

8. **Would you consider the use of this device to be minimal risk? Why or why not?**
   Yes – CPAP as a whole and this machine in particular have been rigorously studied for application in obstructive sleep apnea at the same pressures we will be using the machine. The short term, monitored nature of this study will allow a patient to immediately cease use if they have any discomfort or other intolerance.

APPENDIX: Recruitment

Recruitment includes identifying, review of records to determine eligibility or any contact to determine a potential subjects interest in the study.

*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 (Morrisons), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.

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

- To "identify" a potential subject refers to steps you plan to take to determine which individuals would qualify to participate in your study. This does NOT include steps to actually contact those individuals.
- If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being identified by the given method.
- Check the methods you plan to utilize:

a.____ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or an Improvement Project (*e.g. Performance Improvement, Practice Improvement, Quality Improvement*).
<u>If you plan to obtain data from the UVa Enterprise Data Warehouse (EDW) please see option b below.</u>

<u>DHHS:</u> Study team requests Waiver of Consent to identify potential subjects.

<u>HIPAA:</u> Allowed under Preparatory to Research if PHI to be accessed.

<u>IMPORTANT</u>
Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

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.
<u>If you plan to obtain data from the UVa Enterprise Data Warehouse (EDW) you are required to submit your request to the CDR. The CDR staff will work with the EDW to obtain the data you need.</u>

<u>DHHS:</u> Study team requests Waiver of Consent to identify potential subjects.

<u>HIPAA:</u> Allowed under Preparatory to Research if PHI to be accessed.

IMPORTANT
Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they who meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

The information from which you are obtaining potential subjects must also have an IRB protocol approval. If this item is checked, enter the IRB # below.

IRB# _____

If obtaining information from the Clinical Data Repository (CDR) insert IRB # 10797

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

DHHS: Study team requests Waiver of Consent to identify potential subjects.

HIPAA: Allowed under Preparatory to Research if PHI will be shared by the health care provider.

IMPORTANT
Keep in mind that PHI may only be given to individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

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)

DHHS: NA
HIPAA: Allowed under Health Care Operations

If this choice is checked, check 3d-INDIRECT CONTACT below.

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

If this choice is checked, check 3d- INDIRECT CONTACT below.
DHHS & HIPAA: NA

f. _____ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.

IRB# of registry/ database: _____

DHHS & HIPAA: NA

If item # a, b or c is checked above and if this protocol involves the use of protected health information do you confirm the following to be true? n/a

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

2. How will potential subjects be contacted?

To "contact" a potential subjects refers to the initial contact you plan to take to reach a potential subject to determine if they would be interested in participating in your study. This may include direct contact by such methods as by letter, phone, email or in-person or indirect contact such as the use of flyers, radio ads etc.

If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being contacted by the given method.

Check the methods below you plan to utilize:

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.

Note: Letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

DHHS/HIPAA: Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:

Keep in mind that if PHI was collected during the identification phase that contact with potential subjects may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- a UVa student working in the UVa HIPAA Covered Entity*
- a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

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.

DHHS & HIPAA: Study team requests a Waiver of Consent and a Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:
Keep in mind that contacting individuals in a clinical setting may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
a UVa student working in the UVa HIPAA Covered Entity*
a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

You should share the following information with the potential subject:

- Your name
- Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them
- Ask if you have their permission to explain the study to them
- If asked about how you obtained their information use one of the following as an option for response.
    - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THEIR UVa PHYSICIAN: Your doctor, Dr. insert name wanted you to be aware of this research study and gave us permission to contact you.
    - We obtained your information from your medical records at UVa.
    - Federal regulations allow the UVa Health System to release your information to researchers at UVa, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.
- IF THE PERSON SEEMS ANGRY, HESITANT OR UPSET, THANK THEM FOR THEIR TIME AND DO NOT ENROLL THEM IN THE STUDY. YOU MAY ALSO REFER THEM TO THE IRB-HSR AT 924-9634.

c.__x__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.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.

DHHS: Study team requests a Waiver of Consent to contact potential subjects
HIPAA: Allowed under Health Care Operations.

d.____ 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.)

The indirect method used (flyer, brochure, TV, broadcast emails) must be approved by the IRB prior to use. The IRB does not need to review any type of script to use when the potential subject responds to the indirect method.

DHHS & HIPAA: NA

e. ____ Potential subjects are not patients. The study does not include obtaining subjects health information. Subjects will be contacted directly via email, phone, letter or presentation in group setting with consent then obtained individually in a private setting.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.

DHHS: Study team requests a Waiver of Consent to contact potential subjects.
HIPPA: NA

3. **Will any additional information be obtained from a potential subject during "prescreening"?**

Pre-screening for IRB purposes is the term used to describe activities PRIOR to obtaining Informed Consent and may not include any research procedures.

The activities may involve pre-screening of potential subjects over the telephone or in person is generally performed to determine their initial eligibility for, and, interest in a study and is a common strategy in the recruitment process.
Questions appropriate for pre-screening address the specific inclusion/exclusion criteria for the study and other issues of suitability, for example, an individual's ability to come to the research site multiple times.
It is not appropriate at this point in the process (i.e. prior to obtaining informed consent/enrollment) to gather information that is not directly related to assessing eligibility and suitability (e.g. obtaining complete medical histories, obtaining blood specimens for lab tests).
An additional telephone script is not required, for this pre-screening process, in addition to any scripts required under Recruitment question # 2.

Yes

Pre-screening questions:

- Have you used CPAP in the last month?
- Do you have any significant cardiopulmonary disease?
- If yes, what diagnoses do you carry?

IF YES, submit any documents that will be used to collect pre-screening information so that the IRB may confirm what questions will be asked.
NOTE: To comply with HIPAA regulations only the minimum necessary information may be collected at this time. This means that only questions pertaining to the Inclusion and Exclusion Criteria may be asked.

IF YES,
DHHS: study team requests a Waiver of Documentation of Consent for Pre-screening questions.

HIPPA:
HIPAA does not apply if:
--no PHI is collected or
--if PHI is collected from a potential subject by an individual from a department that is not part of the HIPAA covered entity.

HIPAA does apply if the collection occurs by individuals* who work in a department that is part of the HIPAA covered entity.

In this case the collection will be covered under Health Care Operations/

These individuals are those that meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

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

IF YES, will you collect HIPAA identifiers with the health information?No

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)?**

HIPPA:
If the individual, obtaining consent, works under the HIPAA Covered Entity consenting is covered under Health Care Operations.

If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

The consent process will take place in a separate room from the clinic room. The patient will voluntarily agree to move to this space to proceed with the consenting process. The consent will be reviewed by either a sub-investigator or by a clinical research coordinator.

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

►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.
Functionally, it would require another trip for a set of procedures that will take less than 15 minutes. It would be unreasonable to ask the subject to return another day and financially irresponsible to pay for such an inconvenience.

►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.
If they have any reservations, they will be allowed to consider the study and return if desired.

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?
It will be explicitly conveyed that we are in no way providing treatment to them and this is fully to further our understanding of Eustachian tube function.

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 is:
-personal information that can lead to identity theft if exposed or
-data that reveals an individual's health condition and/or history of health services use.
Protected Data (PHI) a type of Highly Sensitive Data, is data combined with a HIPAA identifier
Identifiable Data under HIPAA regulations is considered to be *Highly Sensitive Data at UVa.*
A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Moderately Sensitive Data* at UVa. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.
Will not include subjects age if older than 89 or subjects DOB if older than 89.

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	Recipient is alerted to the pending transmission and

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.	
May NOT be stored in places like UVaBox, UVaCollab, QuestionPro. May also NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	May be stored in places like UVaBox, UVaCollab, 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.*