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# Is alternative transport a viable option for Norfolk Fire-Rescue?

Nicholas Edward Nelson

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IS ALTERNATIVE TRANSPORT A VIABLE OPTION FOR NORFOLK FIRE-  
RESCUE?


By  
NICHOLAS EDWARD NELSON  
B.S., Glenville State College 1998


A thesis submitted to the Graduate Faculty  
of the University of Richmond  
in Candidacy  
for the degree of  
MASTER  
Human Resource Management

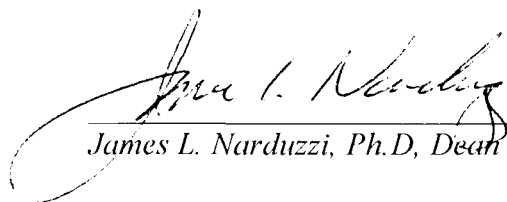
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I certify that I have read this thesis and find that, in scope and quality, it satisfies the requirements for the degree of Master of Arts/Master of Science.

  
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## ABSTRACT

Is Alternative Transport a Viable Option for Norfolk Fire- Rescue?

Nicholas Edward Nelson submitted for Masters in Human Resource Management

University of Richmond 2007

Directed by Professor Dr. Marcia Gibson  
(148)

Emergency medical providers transport 911 patients who do not warrant emergency room (ER) transport via ambulance. This study's purpose was to determine if prehospital care providers, using established protocols, could identify patients accurately to be seen by a physician but require ambulance transportation. Fourteen agencies have initiated emergency medical service (EMS refusal). Alternative transport options would free paramedics to respond to life threatening emergencies, while allowing low acuity patients ER access. Ninety-three study patients were enrolled and transported to emergency departments (ED) via taxi. EMS determined eleven patients met enrollment criteria though refused participation in the study. Nine taxi transported patients were admitted to the hospital. None of the study participants required ED blood transfusions, emergent procedures, or suffered an adverse event attributed to delay in ED arrival by taxi. The study indicates that in its present status, Alternative Transport is not a viable option for Norfolk Fire-Rescue.

## ACKNOWLEDGEMENTS

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# IS ALTERNATIVE TRANSPORT A VIABLE OPTION FOR NORFOLK FIRE-RESCUE?

## **Introduction**

In the City of Norfolk emergency medical providers are called upon to transport patients whose conditions are non life threatening. Patients with minor complaints or chronic illness often call 911 but do not warrant transport to the emergency room via ambulance. Inappropriate use of Emergency Medical Service (EMS) can prolong ambulance response time to true emergencies.

### *The Purpose of This Study*

This study's intent is to determine if an alternate transport mechanism was available to transport minor medical problems to the emergency room, would it affect patient outcome? The United States health care system is currently in a state of crisis related to funding and coverage. Most would not argue that basic health care should be an available human right to all Americans and most would also agree that our current system is not working. Today, over 45 million Americans are uninsured and another 16 million people are underinsured (Schoen et al, 2005).

The state of the healthcare system in the United States has forced citizens to seek care from tertiary centers instead of primary care centers. Citizens are turning to emergency medical services (EMS) and emergency rooms (ER) for primary care. The reason for this may be attributed to lack of health care coverage, lack of education, or general socioeconomic status. Citizens may be unaware that their complaints are not life or limb threatening. Citizens' turning to EMS and ER's for primary care causes an

increase in the use of ambulances for non-emergency conditions and places a strain on the providers and the EMS system when there are not enough transport units to respond to emergencies. The ability of EMS providers to offer an alternative means of non-emergent transport for patients with minor medical complaints is a rarely sanctioned concept in U.S. EMS systems.

Norfolk, Virginia is the city used for this study. On a daily basis, Norfolk's paramedics find all transport units in the city out of service on various calls. Historically, Norfolk Fire-Rescue (NFR) has had the ability to dispatch to the scene a paramedic assigned to a non transport apparatus to begin evaluation and treatment of the patient.

### *Rationale for Selection*

This section provides the reasons for selecting the topic and the location for this study.

Norfolk's paramedics encounter situations daily when all transport units in the city are out of service either responding to calls, for vehicle maintenance, or training. Why is this happening? Are these calls necessary? The state of the healthcare system in the United States has forced citizens to look for care from non traditional sources. As mentioned earlier citizens are turning to emergency medical services (EMS) and emergency rooms (ER) for primary care. Citizens seeking other sources for care, cause an increase in the use of ambulances for non-emergency conditions and places a strain on the providers and the EMS system when there are not enough transport units to respond to emergencies.

### *Significance of the Topic*

The significance of alternative transport can be seen readily when looking at the literature and what it says about the overburdened service requirements placed on EMS organizations in the U.S., not to mention NFR.

Currently, U.S. EMS is being overburdened with a high volume of patients' complaining of low-acuity illness or injury (Billittier et al, 1996). Inappropriate 911 calls cause added strain to a system that is already clogged with non emergent requests. This causes response to true emergencies to be delayed. This also leads to a common complaint among EMS providers as to job dissatisfaction.

Alternative transport could help to alleviate this problem. Prehospital care providers may be able to identify persons and screen them utilizing a pre-determined set of criteria. The patients that could utilize this system are those who may need to be evaluated by a physician, but whose condition is stable and will not deteriorate if they are not transported by ambulance.

### *Methodology Overview*

This study is intended to prospectively determine if an alternate transport mechanism was available to transport minor medical problems to the emergency room, would it affect patient outcome? A twelve thousand dollar grant was obtained by Dr. Barry Knapp, associate professor of Eastern Virginia Medical School to conduct this study. The investigators did not receive any compensation for the study and the money was used to offset administration costs as well as the actual transport of the patients. The intent was to enroll 200 patients into the study. The end result of this study was to determine if prehospital care providers could accurately identify patients using

established criteria (Appendix E) who need to be seen by a physician but not necessarily be transported by ambulance.

There are five agencies currently that have EMS initiated refusal, but none of these agencies offer alternative transport as an option.

The patients were picked by Norfolk Fire Rescue (NFR) providers as being appropriate for EMS initiated refusal and admission into the *Alternative Transport Study*.

### **Definitions**

For the purpose of this study the following terms are provided with their intended definitions as they apply to this study.

1. Emergency Medical Service (EMS) – A system of providers responsible for providing pre-hospital (or out-of-hospital) emergency care. Composed of paramedics and emergency medical technicians (EMTs) to provide emergent medical care to patients with sudden medical emergencies or accident victims.
2. Paramedic - is a specialized health care professional who responds to medical and trauma emergencies in the pre-hospital (out-of-hospital) environment for the purpose of stabilizing and transporting the patient to an appropriate medical facility, usually by ambulance.
3. Advanced Life Support (ALS) - Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.
4. Alternative Transport – A means other than ambulance transport to the emergency room for minor medical or superficial injuries as defined by this studies protocol. For the purpose of this study the alternative transport is a taxi.
5. Emergency Medical Service initiated refusal of transport (EMS-IROT) - An instance when EMS determines to refuse transport of a patient.
6. Patients- Subjects that are entered or asked to take part in this study.

## Delimitations

This section will list some of the delimitations of this study and key assumptions.

There are two basic questions to address that will not be covered in this study:

- 1) *Does the patient need to go to the hospital?*
- 2) *Do patients need to go by ambulance?*

These are two different and distinct questions. Research has shown that a paramedic should NOT determine if a patient needs to go to an Emergency Room. Multiple researchers have made the statement, paramedics cannot reliably predict which patients do and do not require ER care. Paramedics in the field do not have access to such tools as X-Ray, lab equipment and other invasive machines to determine injury or illness.

Paramedics can determine life threatening illness or injury, but they do not have the equipment available to diagnose all patients in need of medical attention. In the literature review section several of these studies will be examined that were conducted about a paramedic's ability to accurately triage and make a determination if a patient needs treatment in the emergency department.

In 2003 a report was released that had conducted 28 separate studies from 1980 through 2002 using a multitude of criteria to determine the paramedic's ability to effectively triage (Mann et al, 2003). Research was conducted to determine if a paramedic could triage, or refuse transport accurately, but there was never a mechanism tested to determine if once the paramedic determined the patient's condition to be non critical, would the patient's care be jeopardized if transported by an alternative means.

## Research Questions

### *Questions*

This research project *will ask the* following questions:

1. Can a paramedic respond to a 911 call, accurately triage (assess) the patient, and then, properly refer them to alternative transport?
2. Will the patient outcome be adversely affected by arriving via taxi and not ambulance?

### **Client**

Norfolk Fire- Rescue (NFR) provides fire and emergency medical services to the 750,000 citizens and visitors of Norfolk, Virginia on a daily basis. Service is provided 24 hours a day, 7 days a week, and 365 days a year.

The mission statement for NFR is “to assist the public in the protection of life and property by minimizing the impact of fires, medical emergencies and other potential disasters or events that affect the community and environment” (Norfolk Fire-Rescue, 2004).

#### *NFR History.*

NFR is the third oldest, fully paid fire department in the United States. The fire department started in 1751 with an imported fire apparatus from London, England. The first organized firefighting company was established in 1788. The fire department was an all volunteer company for the first one hundred and twenty years. Then, in 1871, a riot resulted in the deaths of rivals from several volunteer companies. This forced the city

council to take action and, on December 15, 1871, the Norfolk Fire Department (NFD) was established (Dibacco, 2003).

The NFD, as it was known for the first one hundred and twenty years, evolved into Norfolk Fire and Paramedical Services (NFPS) in 1991. Then, in 2001, Norfolk Fire Rescue (NFR) was born. The name has changed three times as has the services that are provided by NFR. There are approximately 500 personnel that make up NFR. NFR has firefighters, paramedics, shock traumas, secretaries and even a business manager. The fire department is also unique in that numerous jobs are performed by sworn firefighters. Captains and Chiefs that once rode on fire trucks now carry out most of the specialized jobs that are performed as well as all of the administrative duties.

The merger of the NFD with Paramedical Rescue Services (PRS) came out of necessity to provide a service to the citizens. Until 1969, the NFD responded to medical emergencies and the patients were transported by Norfolk Police Department in station wagons. A private ambulance service operated in Norfolk for about two years until it went out of business. This forced the city in 1971 to take action and they formed the Norfolk Paramedical Rescue Services (PRS) (Dibacco, 2003).

Fire departments around the country were extremely busy in the 1970s and 1980s but, as fire prevention and building safety codes improved, fires decreased. The city governments were not willing to pay for fireman to wash their trucks and sit in front of fire stations. The fire service felt that it had to do something to justify its existence. At the same time that calls for fires were decreasing, EMS calls were increasing. Norfolk was no exception. PRS could not provide ambulances to the citizens in the six minutes or less, the national standard, as well as the goal they strived to achieve (Dibacco, 2003).

In 1991, the city merged the two departments to provide services to the city in the most economical and efficient manner possible.

#### *NFR services*

Norfolk Fire – Rescue offers more than just EMS, and putting out fires for the citizens and visitors to Norfolk. NFR provides hazardous materials (HAZMAT) response, technical rescue services, marine and water rescue response, arson investigation, fire prevention, child safety seat installation, smoke detector installation, as well as public education programs.

#### *NFR Statistics*

NFR has 14 stations strategically placed throughout the 65.98 square miles that make up the City of Norfolk. There are 11 ambulances, 14 engines, 7 ladder companies, two heavy rescue companies and 4 battalion chiefs. In 2006 NFR responded to 40,557 calls. (Evans 2007). Norfolk Fire Rescue is allotted 508 employees. This number does not represent the department's true strength as it does not take into account retirements, resignations and employees that have not been replaced. The make up of the department is as follows, One Fire Chief, One Deputy Fire Chief, Four Assistant Chiefs, 16 Battalion Chiefs, 48 Captains, 40 Lieutenants, and 379 Firefighters, additionally there are 23 students in recruit class. There are 19 civilians assigned to various administrative jobs within NFR.

Currently, NFR has 500 employees this number includes recruits now in the fire academy. Of the 500 employees 361 are medical providers, with 268 Basic Life support providers and 93 Advanced Life support technicians (paramedics and intermediates). For the period of 2001 thru 2006 Norfolk Fire-Rescue averaged responding to 36,210



emergency medical calls a year. EMS calls totaled by medic are found in Table 1-1 for 2006. Statistics compiled by Norfolk Fire-Rescue, from NFR on Scene January 2007 Edition.

**Table 1-1 Calls for 2006 by Medic**

<b>MEDIC</b>	<b>Jan</b>	<b>Feb</b>	<b>Mar</b>	<b>Apr</b>	<b>May</b>	<b>June</b>	<b>July</b>	<b>Aug</b>	<b>Sept</b>	<b>Oct</b>	<b>Nov</b>	<b>Dec</b>	<b>YTD</b>
<b>Medic 1</b>	280	316	318	321	340	351	361	326	343	312	311	294	3873
Medic 2	285	299	312	320	342	339	345	305	270	319	339	305	3780
<b>Medic 4</b>	187	206	208	225	213	212	222	205	196	201	189	187	2451
<b>Medic 7</b>	190	215	234	225	235	208	270	238	233	211	221	193	2673
Medic 8	135	155	172	179	191	176	207	211	172	162	153	147	2060
<b>Medic 9</b>	226	230	263	261	270	246	335	264	237	255	230	236	3053
Medic 10	222	253	275	260	260	239	263	247	225	248	241	248	2981
<b>Medic 11</b>	235	246	231	273	267	266	256	261	252	259	225	270	3041
Medic 13	206	223	234	231	243	240	296	266	221	210	195	247	2812
<b>Medic 14</b>	274	291	311	284	284	320	325	331	317	327	289	291	3644
Medic 16	184	175	193	190	213	197	216	196	193	185	195	184	2321

### *Reasons for Selecting NFR*

Fortunately, Norfolk Fire-Rescue (NFR) has always been able to dispatch a paramedic assigned to a non transport apparatus to the scene to begin evaluation and treatment of the patient. NFR has service goals of four minutes for triage and treatment to begin and six minutes to provide advanced life support (ALS) transport units. There are times no ambulances (NFR transport units) are available to transport the patient to the closest ER, but the triage and treatment of the patient can begin within the four-minute goal. The second goal of providing an ambulance in six minutes or less sometimes cannot be met due to out-of-service transport or in-service transports providing non emergent care.

With these service goals in mind, when patients with minor complaints or chronic illness call 911 but do not warrant transport to the ER via ambulance, an alternative needs

to be imposed. EMS systems are designed to rapidly treat and transport seriously ill or injured patients to the ER.

Norfolk's predicament of meeting its two goals and its citizens using EMS and ER for non emergent care needs seemed to make it a good choice for this study.

### *Outline of the Thesis*

Chapter One-- Introduction provides an introduction to the thesis with an explanation of the topic, reasons for selecting it and its significance. This chapter provides background of the topic, hypothesis and questions considered, delimitations and key assumptions, brief description of the methodology and client organization under study.

Chapter Two--Literature Review provides a background of the literature that was reviewed to determine if the need exists to find some form of alternative transport for patients calling 911. Literature was also reviewed to determine if this would be appropriate to Norfolk, VA specifically.

Chapter Three—Methodology provides information on how the patients were identified, selected, evaluated and given the opportunity to submit or refuse taking part in the research.

Chapter Four—Application, Findings, and Recommendations provide the information that was obtained, evaluated and tabulated to determine the success or failure of the research.

Chapter Five—Conclusion provides recommendations that came out of the research for Norfolk Fire-Rescue. As well as topics that were identified during the research that will require further study.

As indicated earlier the purpose of this, study is to determine if an alternate transport mechanism was available to transport minor medical problems to the emergency room, would it affect patient outcome.

In this chapter you also were provided the rationale for selection of this topic for study, the significance of the topic, a brief description of the methodology, definitions for ease of understanding, study delimitations and key assumptions, reasons for selecting the organization for the study with a brief description of the organization, and an outline of the thesis.

Chapter two provides a review of the literature search related to this topic and the research issues.

## **Chapter 2**

### **Literature Review**

There has been a great deal research in the area of inappropriate use of emergency medical services transport, paramedics using guidelines accurately triaging patients, and paramedics accurately identifying patients who do not require emergency department care. This chapter will look at papers, magazines, and sources of research that have looked at the following topics related to the use of alternative transport in the United States: accurately identifying patients, guidelines for triaging patients accurately, inappropriate use of emergency medical services transport, and alternative transports.

#### **Accurately Identifying Patients**

There is no single answer to these questions posed above and a thorough case-by-case assessment is essential. A series of studies conducted throughout the U.S. have shown that Emergency Management System (EMS) providers have difficulty evaluating patients and determining whether alternative means of transport may be appropriate. This inability to fully assess a patient largely results from the lack of laboratory facilities and radiography in the field.

There are numerous articles written on providers' inability to properly identify which patient needs to be seen in the ER. In fact, most EMS systems transport all patients that call 911 unless the patient initiates the refusal (Knapp Riley, & Powers, 2005).

Another study from 2002 found that in the urban system studied, "paramedics cannot reliably predict which patients do and do not require ER care" (Silvestri S 2002, 387-390). This study took place in a large Florida county (with more than one million

residents) with a two-tiered, dual response to 911 calls, with eight local fire departments with ALS capability and a private ALS ambulance transport service. The study found that for 85 cases, in which paramedics felt that ER transport was not necessary, 27 patients met the criteria for ER treatment, 15 were admitted, and five were admitted to an intensive care unit. These two studies make it clear that when paramedics make a decision against transporting a patient, that decision carries a high level of risk

"EMS can't even really do a full physical exam with a patient's clothes on," says Mark Hauswald, MD, an emergency physician and associate dean for clinical affairs at the University Of New Mexico School Of Medicine in Albuquerque, and the author of one of the studies. (Hauswald, M. 2002, 383-386) Hauswald's study was a prospective survey that linked medical record review. Paramedics completed a brief questionnaire for each patient transported to the university hospital in a one-month period (Hauswald M 2002). Ambulance transport was defined as "needed" if the charted differential diagnosis included diagnoses that could necessitate treatment in the ambulance. Emergency room (ER) care was defined as "needed" if treatment of these diagnoses would necessitate resources not available in local urgent care centers. In his study, paramedic's recommended alternative transport for 97 patients, 23 of whom needed ambulance transport, and recommended non-ER care for 71 patients, 32 of whom needed ER care. The study concluded that paramedics can't safely determine which patients do not need ambulance transport or ER care (Hauswald M 2002J).

Finally, another study from Minnesota looked at paramedics who worked eight-, 12- and 16-hour shifts to determine whether the non-transport rate varied in the final hour of the paramedics' shifts. This study concluded, "There were statistically significantly

smaller numbers of patients signed off in all phases of the eight hour shifts." The study recommended that "decreasing shift lengths to eight hours will significantly reduce the number of patient sign-offs and result in less potential liability."(Caulkins C.G. 2001, 83-85).

### **Guidelines for Triage Patients Accurately**

W. Ann Maggiore, JD, NREMT-P, in a recent article for *JEMS Magazine* looked at five different studies that related to EMS providers ability to triage and find appropriate interventions for patients. A study from the Oregon Health Sciences University evaluated the use of protocols allowing providers to determine the need for treatment and transport. This study concluded that 3-11% of patients who EMS determined did not need transport later had a critical event, and it recommended that EMS systems should determine what rate of "undertriage" was acceptable (Schmidt. T.2000).

The authors of the *Oregon Health Sciences University Study* followed up a year later with another publication looking at hospital follow-up of patients categorized in the field as not needing an ambulance, using a set of EMS protocols (Schmidt. T. 2001). The second study concluded that the protocols led to a 9% undertriage rate and further found that patients with psychiatric complaints and dementia were at high risk for undertriage by EMS.

### **Inappropriate Use of Emergency Medical Services Transport**

The literature reviewed points to the paramedic's inability to determine if the patients need to be seen in the ER. This study does not support giving EMS provider's authority to deny patients medical care. There still needs to be research conducted which

was not included in this project to determine if the persons that were admitted to the hospital needed the emergent treatment available in the ambulance. None of the research gave any information on whether admitted patients that arrived via taxi, personal vehicle, or any other means were jeopardized by their lack of ambulance transport.

The examined literature did show a common trend in undertriage. Most of the literature discussed patients falling into one of the following categories: pediatric, dialysis, psychiatric, and the immunosuppressed. The examined literature focused on whether a provider could correctly triage patients who need medical care. There was only one study conducted prior to this that explored if alternative ways for the patients to reach the ER (Knapp et al, 2005).

In 1998 D. Jaslow, Johnson, and Moore authored the article for *Prehospital Emergency Care*, titled “EMS-Initiated Refusal and Alternative Methods of Transport.” They surveyed the 200 largest cities in the United States by telephone regarding EMS-initiated refusal policies, involvement of physicians in the decision-making process, and the presence or absence of alternatives to EMS transport. Seven of the EMS systems that allow refusal of transport also have a formalized alternative transport program in place (Jaslow, Johnson, and Moore, 1998).

Finally, the study found that only 19 of the cities surveyed offer some type of alternative to ambulance transport. Once the paramedic has either used a protocol to determine the patient did not need transport or spoke to a physician, then the patient was given alternative means of transportation, i.e. van, taxi, or non emergent transport vehicle (Jaslow, et al. 1998).

### **Alternative Transports**

Thomas Beers, a firefighter/paramedic with the Cleveland Heights (OH) Fire Department wrote in *Fire Engineering and EMS*, “There is a protocol tool out there that is becoming more and more popular within medical commands. It is called an “Alternative Transport” protocol. Alternative transports, if you are unfamiliar with the idea, list chief complaints and patient presentations that a local medical director has tagged as not requiring ambulance/EMS transport. The mechanism for selection and quality review would be critical to the success of the program to assure the alternative transport was not abused” (Beers, 2006, p14).

Perhaps this is where firefighting has succeeded and EMS has failed. It is true that through public education about fire safety and the importance of smoke detectors, fire fatalities and the number of fires in the United States have declined over the past several decades. But with very little to no public education for the past 30 years about how EMS should be used, the system has become clogged with non emergent calls. It could be a difficult task to change the culture, both from the citizens and the EMS system perspective.

### **Norfolk Fire-Rescue Research**

Dr. Barry Knapp (2005), Operational Medical Director of Norfolk Fire-Rescue undertook a study to determine if there was a need for alternative transport. The study was a prospective, cross-sectional survey of large US EMS systems, designed to determine which jurisdictions permit EMS-IROT and to describe characteristics of each. Dr. Knapp conducted a telephone survey that contacted 100% (200) of the target population EMS providers. Fourteen (7.0%) agencies were found to have EMS-IROT



protocols, though nine (4.5%) of these agencies required online physician approval. Average annual call volume of the five autonomous EMS-IROT agencies was 70,800, while their EMS-IROT protocols have been in existence a mean of 19.8 years. No agency offered a no-cost alternative transport mechanism. Autonomous EMS-IROT programs were surveyed on a scale of 0–10 (0 lowest, 10 highest) and found to have a mean of 4.3 for improving ambulance availability and a mean of 7.0 for provider satisfaction. (Knapp et al, 2005)

EMS-IROT, without direct medical oversight, is sanctioned in only five of these 14 systems. In these five systems, EMS providers are allowed to refuse transport based on established protocols and are not required to consult with an online medical control physician. In all five of these systems, the agency has specific written protocols governing the appropriate use of this policy. Similarly, each of the five systems allows only paramedics to initiate refusal of transport. The remaining nine systems all require online medical control consultation and approval in order to refuse patient transport. Two (1%) of the 200 systems surveyed have policies that allow for EMS-IROT frequent abusers of the EMS system. These policies are only utilized to refuse the transport of specific patients with a history of EMS abuse, and thus, are not truly EMS-IROT programs. Three (1.5%) of the 200 EMS systems did have an EMS-initiated refusal protocol at one time but have since terminated the program (Knapp et al, 2005).

In addition, the five EMS systems having EMS-IROT policies not requiring direct medical oversight were surveyed to determine the characteristics of their particular agency and refusal policy. According to the 2005 *Journal of Emergency Medical Services (JEMS)* "200-City Survey," 71.3% of U.S. EMS systems allow providers to treat patients

without transporting them, and 35.7% have a policy that allows EMS to refuse transport. Much of the research that has been conducted on this topic points to the inadequate prehospital triage and assessment conducted by providers as the main concern for not allowing providers the right to refuse transport in the field (Williams, 2006).

It should be noted that the programs not only improved ambulance availability but assisted with provider satisfaction. This is a concern for Norfolk Fire-Rescue as it is becoming more difficult to retain providers. This will not be discussed in this research but is one of the topics that require further research this project has identified.

In this chapter relative articles and papers were reviewed to determine if there was a need to study this topic. There clearly is a need for an alternative mechanism to provide the public transportation to medical care. None of the articles reviewed were in favor of allowing prehospital providers to refuse medical care to a 911 caller. The literature clearly reveals prehospital care providers have difficulty determining which patients need to be evaluated by a physician. It is also noteworthy that the number of EMS calls for service and visits to the emergency room are steadily increasing. The literature did show that patients that should have been added to the list of not eligible for inclusion in the Norfolk study would be the dialysis and immunosuppressed patients. Norfolk was inline with not allowing psychiatric or pediatric patients to take part in the study. The common theme of the literature review was undertriage by EMS personnel.

In the next chapter, the author provides actual research methodology, the criteria for patient selection, operationalization of the research question, and variables for analysis.

## **Chapter 3**

### **Methodology**

The purpose of this study is to determine if an alternate transport mechanism was available to transport minor medical problems to the emergency room, would it affect patient outcome.

#### **Study Design**

The study design is a non-experimental causal design. A causal relationship entails some time elapse between the occurrence of the cause and the consequent effect. As casual observers, the data that is reviewed for the purpose of this design will be collected as emergency events unveil themselves during the study period. The data that is reviewed for the purpose of this study are two variables from a larger Eastern Virginia Medical School (EVMS) study. A twelve thousand dollar grant was obtained by Dr. Barry Knapp, associate professor, EVMS to conduct this study. The investigators did not receive any compensation for the study and the money was used to offset administration costs as well as the actual transport of the patients. Dr. Knapp hoped to enroll 200 patients into the study. The end result of this study was to determine if prehospital care providers can accurately identify patients using established protocols who need to be seen by a physician but not necessarily be transported by ambulance.

#### **Target Population/Sample**

The target population for this study consists of patients who call for 911 for ambulance transport. The study anticipates a sample of 200 over a six-month period.

The selection criteria for participation will be based on those screened by EMS as eligible for alternative transport and met the requirements listed on the “Subject Consent Form—Eastern Virginia Medical School Institutional Review Board” which details the scope and breadth of the study to include reason for the study, risks to the patient, actions taken if injury should occur, and confidentiality agreement to name just a few areas of the form.

This non-experimental, causal design required locating about 200 people in the City of Norfolk to participate for a six-month period starting in the spring 2005. This study included only people who chose to take part. Each participant was advised to take time to make the decision to participate and to feel free to ask any questions. If a participant refused to participate, transportation in an ambulance was provided to the nearest Emergency Department as outlined in the City of Norfolk's EMS Standard Operating Procedures.

As part of this design the ambulance crew identified the potential participant. Per EMS standard of care, the Advance Life Support (ALS) provider evaluated the patient. Vital signs including pulse, blood pressure, and breathing rate were performed as well as a history and physical exam.

After an initial evaluation by the ALS, the patient was offered the opportunity to participate in study if medically stable and did not meet any of the criteria for elimination. Once the patient agreed to participate in this study a transportation voucher was provided and the EMS crew notified the Taxicab Company to transfer the patient to the nearest Emergency Department. The patient may also choose to contact the Taxicab also. For this study arrangements were made with: Black and White cabs and Norfolk Checker Taxi service.

Data for the study design was gathered from the “Alternative Transport Consent Form,” the “Alternative Transport Taxi Voucher,” Norfolk Fire-Rescue EMS Run Reports, and hospital ER and inpatient records. The data was then collected and entered once a month into the Excel Spreadsheet for review and interpretation by this researcher. There were seven patients that left the ER prior to being triaged, took the taxi voucher and did not check into the ER, or left the ER after triage but prior to being seen by the physician.

### **Procedure and Patient Selection**

The patients were selected by NFR providers as being appropriate for EMS initiated refusal and admission into the “Alternative Transport Study.” This study was granted exemption from full review by the Eastern Virginia Medical School Institutional Review Board (IRB) as well as the University of Richmond’s IRB (Appendix A & B). The patients were evaluated and chosen for inclusion by NFR Paramedics using 28 criteria for screening listed on the “Alternative Transport Checklist” (Appendix E) provided by Dr. B. Knapp, Associate Professor EVMS and Operational Medical Director of Norfolk Fire- Rescue. In order to be used for the study none of the 28 criteria could be present. If the patient did not meet any of the 28 criteria, the paramedic performed the steps in Table 3-1, Patient Consent:

**Table 3-1 Patient Consent**

1. Explain research study to patient
2. If patient is agreeable, have patient sign consent forms found in binder; if patient refuses cab transport via ambulance and write down patient info on unused taxi voucher
3. Call taxi company at 855-4444 or
4. Give patient cab voucher
5. Retain one copy of consent
6. Put copy of consent in binder located at Fire station

Participants signed the “Subject Consent Form” if they agreed to participate in this study (Appendix C). The “Subject Consent Form—Eastern Virginia Medical School Institutional Review Board” detailed the scope and breadth of the study to include why the study was being conducted, risks to the patient, actions taken if injury should occur, and confidentiality agreement to name just a few areas of the form. The paramedic would then complete the “EMS Taxi Transport Voucher” for the taxi company to assure reimbursement for the taxi company (Appendix D).

### **Research Team and Training**

The research team was comprised of this researcher, the principal investigator for this study, Dr. Knapp, the principal investigator for the larger study, members of his research team, Dr. Johnathan Sheele M.D. Eastern Virginia Medical School Department of Emergency Medicine and Jennifer Prince R.N., MS Sentara Norfolk General Hospital, Norfolk Fire-Rescue (NFR) Field Training Instructors (FTI), and Paramedics that completed the training. Data collectors initially consisted of just the NFR FTI personnel for a total of 30. This group was expanded to include more providers with the hopes of reaching 200 patients by the end of 2006. There were a total of 50 providers that were eligible to enroll patients. The paramedics that were department FTI’s were selected by the training division, Dr. Knapp and the administrative staff of Norfolk Fire-Rescue. The second groups of providers were also chose by the same individuals and required to have 2 years of experience and be paramedics. None of the EMT-I’s or any paramedic with less than 2 years was allowed to participate in the study. The paramedics were stationed at various fire stations in the city and could enroll participants from the ambulance, or other apparatus, i.e. engine, ladder or rescue; they were assigned to for their duty day.

All data collectors completed training in the scope of the study as well as a class on the HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPPA) and research methods conducted by EVMS.

In conducting this research study, it was determined that it may be necessary for the research team to send information about the test subjects' health to persons in other organizations. For example, Dr. Knapp or members of his research team will report the results of the study-related activity to Tidewater Emergency Medical Council (TEMS), the sponsor of the study. This information may include what is call "protected health information (PHI)," which includes personal information about the patients. All information is and will be maintained in strict confidence and only disclosed as required by law. However, protected health information will be disclosed if required by law. Once the PHI is disclosed for research, such as to the sponsor, federal privacy laws may no longer protect the information.

### **Apparatus**

The data of the study were continually monitored by Dr's. Knapp and Sheele to assure patients were not being harmed or placed in any jeopardy as the study progressed. A Microsoft Office Excel spreadsheet was used to track the patients' outcome as they were enrolled; this was an ongoing process. The spreadsheet consisted of 79 columns labeled with patient demographics, response times, complaints, vital signs, procedures, and outcomes and 105 of rows labeled with patients names. There were a total of 78 variables tracked for the purpose of the larger study. The only two evaluated for the purpose of this study were: 1) proper enrollment of patients and 2) documentation of any adverse event occurring as a result of inclusion in the study. This data was then used to

determine the amount of under triage for NFR providers. The date was entered bi-weekly into the spreadsheet by this investigator. The data was taken from EMS run reports, ED records, inpatient records and taxi records.

### **Variables for Analysis**

During the study period patient information, dispatch and response times, triage times, and various other variables were collected for analysis. The dependent variable for this research was: *Is Alternative transport a viable option for Norfolk Fire Rescue?* The dependant variable is what we hope to learn by conducting this research. The information or independent variables were: patient properly enrolled and adverse event associated with enrollment. Factors that might impact these were transport times via ambulance versus taxi, triage times for patients that arrive via EMS versus taxi, total time patients were in the hospital, and differences in vital signs documented by EMS and triage staff at EDs. Patient information was collected from NFR patient run reports, hospital charts, and information supplied by the taxi company. Each patient's chief complaints, vital signs (pulse, temp, blood pressure, respirations, and blood oxygen saturations) were evaluated for proper selection of patients for enrollment. Analysis was conducted to determine transport times via ambulance versus taxi, triage times for patients that arrive via EMS versus taxi, total time patients were in the hospital, and differences in vital signs documented by EMS and triage staff at ED's. Analysis was also conducted to determine Dispatch chief complaints, EMS chief complaints, triage chief complaint, and finally physicians' chief complaints. The physicians that over saw the research looked at whether or not the patients were admitted, labs, x-rays, or other procedures were



performed and then determined if the patients were properly enrolled in the study. Finally, it was determined if an adverse event due to study participation occurred. As stated there were 78 independent variables collected for research, of those two are examined for the purpose of this study. Was the patient properly enrolled and was there an adverse event associated with enrollment?

### *Questions*

This research project *asked the* following questions:

1. Can a paramedic respond to a 911 call, accurately triage (assess) the patient, and then, properly refer them to alternative transport?
2. Will the patient outcome be adversely affected by arriving via taxi and not ambulance?

The threats to the independent variables include the use of different providers to conduct the research, we had no control over how many patients would be enrolled and the provider's reluctance to take part in the research. The key variables were the patients properly enrolled using the established protocol (Appendix E). The other variable did an adverse event occur, was collected and determined by the physicians that over saw this research. The physicians used established medical criteria and no patient required emergent surgery, blood products or any type of advanced interventions upon arrival at the ED. In this section we reviewed the criteria for patient selection, operationalization of the research question, variables for analysis and statistical approach for summarizing the findings of the research. The next chapter will analyze the actual data that was collected during this study.

## **Chapter Four**

### **Data Analysis**

Though prehospital delays were relatively short, hospital admission rates for patients determined by NFR to be candidates to an alternative transport mechanism were unacceptably high. There were 9 patients ultimately admitted to the hospital or 8.7% of the patients enrolled in this study. The patients that were admitted did not suffer any adverse effects due to admission into the study. In a large urban area such as Norfolk, VA the transport time for EMS to ED is relatively short. The patients that arrived via EMS only arrived eight minutes sooner than those transported by taxi. In the summary and recommendations section the significance of this particular variable will be examined.

Below is a listing of the data collected from the 104 patients. The data present the averaging of data collected with regard to age, time on scene, time out of service, arrival time of taxi called, triage time via EMS, triage via taxi, time from initial 911 call to ER triage, adverse events, and hospital admissions averages. Data was collected on 57 males and 47 females of whom 10 were homeless. Ninety-one and three tenths percent were properly triaged. Eight and seven tenths percent were improperly triaged.

Table 4-1, Overview of Data contains the documented demographic data that for the 104 participants used in this study.

**Table 4-1 Demographic Data**

<b>Description</b>	<b>Data</b>
Total Number of Patients	104
Female	47
Male	57
Homeless	10
Average Age	30.5

The “Alternate Transport Checklist” was used to determine proper enrollment and if an adverse event occurred due to the patient being enrolled into the study. The information was collected from NFR patient run reports, hospital charts, and information supplied by the taxi company. The total number of patients asked to participate in the study was 104, of this number 93 participated. Of the 93 that chose to participate 104 were actually used for the study. The data used to answer the research questions are derived from the larger study conducted by Norfolk Fire-Rescue and Eastern Virginia Medical School. Due to Federal HIPPA laws the actual patient charts, EMS run reports and all information with patient identifiers are being kept in the custody of Sentara Hospital Systems Research Department and retained by the originating agency.

#### *Omission/Errors*

There are parts of the data that did not affect the outcome of this study that were unavailable. Such items as times for taxi arrival and some patient records were not found. There were seven patients that left the ER prior to being triaged, took the taxi voucher and did not check into the ER, or left the ER after triage but prior to being seen by the physician.

The information that was needed for the purpose of this study was collected and evaluated by this researcher. The parts of the data that are blank occurred as a result of improper documentation by providers both prehospital and ED staff, the patients left prior to being triaged or seen in the ED and the researchers were not able to obtain records for some patients due to incomplete triage and EMS run reports. The problems develop when providers take short cuts or do not accurately triage their patients as evidenced by the 8.7% of patients improperly triaged. In this researchers opinion this occurs for a variety of reasons, providers are overworked, lack of medic units, system abusers, and provider experience are several reasons this occurs.

### *Improper Enrollment*

The study identifies nine of the patients that were not properly triaged according to the guidelines for inclusion in this study. Table A-1: Triage Enrollment Data (Appendix E) is a compilation by Voucher Number of patients that were properly or improperly enrolled and whether there was an adverse impact as a result. As can be seen from the data, Item Numbers 15, 17, 25, 35, 54, 68, 69, 84 and 93 were improperly enrolled. The two primary reasons for this are, age and medical complaint, shown in Table 4-2, Reasons for Improper Enrollment. A patient-by-patient description to support these findings is provided in Appendix G in Table A-3. Improper Enrollment Data.

**Table 4-2: Reasons for Improper Enrollment**

#	Reason	Number Enrolled Improperly
1	Medical Complaint	182, 190, 38, 12, 215
2	Age	26, 231, 87, 200

As shown in Table 4-3 Hospital Admissions Data 9.8% of the study patients were admitted to the hospital. This difference is due to the fact that two of the patients that were admitted to the hospital did meet the inclusion criteria for this study. The simple fact that a patient was admitted to the hospital, in and of, itself does not mean the patient was improperly triaged. Patients arrive at the ED and require hospitalization for numerous causes that would not benefit from arriving via ambulance.

**Table 4-3** *Hospital Admissions Data:*

Description	Data
Adverse event due to study participation	None
Hospital Admissions	9.8% (9 out of 104)
Properly triage by EMS based on criteria	91.3% (95 out of 104)
Improperly Triage according to Protocol	8.7% (9 out of 104)

### Statistical Analysis

The following information presents a summary of the data with regard to the patients enrolled, time elements for triage and transportation, hospital admission, and adverse impact. The data collected for study is based on observation and entries made to various forms. The data is collected from these forms, entered into a Microsoft Excel spreadsheet and then simple descriptive statistics are compiled such as averages and percentages. A decision as to the impact of this data is based on the outcome of the patient. If the data showed the patient was inappropriately enrolled or the patient suffered an adverse outcome that would be noted on the spreadsheet. All data was captured and placed in Excel spreadsheets for evaluation and review by this researcher, Dr's Knapp and Sheele. The patient outcomes and medical charts were reviewed to determine no adverse outcomes occurred as a result of inclusion in this study. The times were reviewed to determine the difference in transport times arriving via ambulance and taxi. And

finally, triage by hospital personnel versus evaluation of patients chief complaints by NFR paramedics.

### *Summary of Data*

Ninety-three patients were enrolled and transported to the ED via taxi. Eleven patients were determined by EMS to meet enrollment criteria though refused to participate in the study. Two of the participants were enrolled twice. Average time from taxi dispatch to ED arrival was 11 minutes. The average time of arrival to triage via ambulance was 16 minutes while the average taxi arrival to patient triage time was 24 minutes.

Nine patients (9.36%) transported by taxi were ultimately admitted to the hospital. Most were complicated patients falling into one of the following categories: dialysis, psychiatric and the immunosuppressed. None of the study participants required ED blood transfusions, emergent procedures, or suffered an adverse event that could be directly attributed to the delay in ED arrival by taxi.

The time differences for EMS arrival to triage times were relatively short regardless of arrival mode (ambulance or taxi).

**Table 4-4 Comparison of time to triage EMS vs. Taxi:**

<b>Description</b>	<b>Data</b>
Avg. Time to triage via EMS: 16 Minutes	16 Minutes
Avg. Time to triage via Taxi: 24 Minutes	24 Minutes

Hospital admission rates for patients determined by paramedics to be appropriate for alternative transport mechanism were unacceptably high. The study shows that patients with complicated medical conditions should be excluded from alternative transport protocols.

In this section the actual data used to address the questions were presented and reviewed:

*1) Can a paramedic respond to a 911 call, accurately triage (assess) the patient, and then, properly refer them to alternative transport?*

*2) Were there any adverse impact due to Alternative Transport?*

The study hoped to enroll 200 patients which was not achieved. Only 104 patients were enrolled in the study. The data show that Norfolk has the same difficulties as other areas that have attempted, Alternative Transport or some other form of EMS IROT. Undertriage was the common theme of the review of the literature and Norfolk Fire-Rescue's attempt at Alternative Transport proved to have the same struggle. While no adverse events occurred as a result of the study and no harm was done to any of the participants as a result of taking part in the study, an unacceptable amount of hospital admissions resulted. The patients that were admitted suffered from multiple illnesses which added to the difficulty of evaluating and triaging these patients.

## **Chapter Five**

### **Summary and Recommendations**

In this section the research will be summarized, the findings discussed and recommendations made that could facilitate transport decisions and methods of utilizing an alternative transport mechanism within Norfolk Fire-Rescue. This section will also point out questions that were exposed that need further review and finally topics for future research will be identified.

### **Summary of Findings**

The research clearly shows that Norfolk Fire-Rescue has the same difficulty as other agencies that have attempted Alternative Transport or EMS IROT. The problems develop when providers take short cuts or do not accurately triage their patients as evidenced by the 8.7% of patients improperly triaged. In this researcher's opinion this occurs for a variety of reasons, providers are overworked, lack of medic units, system abusers, and provider experience all add to this occurrence.

As to the hypothesis and research questions, the researcher finds that the data supports the second question and can state that patient outcome is not adversely affected by arriving via taxi and not an ambulance. One hundred percent of the 93 participants had no adverse impact from using the alternate transport.

However, the research is not as confident in drawing the same conclusion as to the ability of the paramedic to respond to a 911 call, accurately triage the patient, and make the proper referral to an alternative transport. In this study the wrong decision was made 8.7% of the time or 9 out of 104. Although the correct assessment was made with



### *Patients Appropriately Enrolled?*

There were a total of 104 patients enrolled into the Alternative Transport Study by Norfolk Fire-Rescue providers. Of those 95 (91.3%) were properly enrolled. The nine (8.7%) that were not properly enrolled were due to paramedics not applying the “Alternate Transport Checklist” correctly. In all nine cases the age or medical condition each patient initially complained of was on the checklist.

### *Adverse Event Due Alternative Transport*

There were no adverse events due to patients’ agreement to participate in this research. The patients’ charts and final dispositions were reviewed. None of the patients that required hospitalization or surgery had any complications that could be related to their participation or to the use of alternative transport. None of the patients care was compromised by the lack of EMS interventions while enroute to the ED, and finally, no significant time difference was noted by patients that arrived via taxi or EMS.

**Table 5-1 Comparison of time to triage EMS vs. Taxi:**

<b>Description</b>	<b>Data</b>
Avg. Time to triage via EMS: 16 Minutes	16 Minutes
Avg. Time to triage via Taxi: 24 Minutes	24 Minutes

### **Recommendations**

The need is greater now than ever before to find an alternative to EMS transport for non emergent patients. The number of EMS providers is shrinking, the calls are increasing, and the demand placed on ED’s to serve as primary care providers is at a critical level. The inability of agencies to staff units in some localities has resulted in services being cut. Norfolk Fire-Rescue has been fortunate, the administration and City Government has not only been able to keep ambulances in service, but was able to add an

additional ambulance in the Poplar Halls area of Norfolk. Providers are being bogged down with non emergent calls. Norfolk Fire-Rescue averages responding to over 100 calls a day. Some agencies have turned to placing paramedics in fast response vehicles with Basic Life Support (BLS) Ambulances to transport patients after evaluation by paramedics. This allows for medically trained providers to monitor patients to the ED while freeing paramedics to respond to illness or injury that require advanced interventions. Quality assurance in EMS run and ED triage reports would assure proper documentation of patient's complaints, vital signs and ultimate outcomes.

Proper documentation allows for allocation of resources and gives administrators support or disproves determining if BLS/ALS ambulances would function within our system.

This researcher recommends that the City of Norfolk develop a policy and procedure for using Alternate Transport for non emergent patients. This researcher believes that with proper training and implementation, the citizens can be better served by ensuring quick transport of both non emergent and emergent patients by implementing this kind of a program.

Finally, protocols for determination of which patients would be appropriate need to be reevaluated. It is clear to this researcher that the results indicate that a training program for implementing the alternate transport program would be necessary. All paramedics would need to be trained on assessing patients that present with minor complaints but have complex medical conditions, i.e. AIDS, dialysis, psychiatric, pediatric, and geriatric to ensure proper transport. The importance of these patients must

be stressed as 4 out of 8 (50%) of the patients deemed inappropriate during the study fell into this category.

### **Topics for Further Review**

**As a result of this study and the literature search other topics emerge for review and study. These topics are listed below:**

1. 911 call versus true patient complaints.
2. Is there a relationship between patient age and severity of complaint?
3. Is there a correlation to patients with primary care versus no provider?
4. Do patient's complaints change upon arrival at ED?
5. Are paramedics not only under triaging but under treating patients?
6. Is there a difference in rates of admission via arrival methods?
7. What is causing the increased use of EMS?
8. Feasibility of tiered EMS response, ALS/BLS responses?
9. What percent of EMS calls are true emergencies?
10. Would public education similar to fire prevention be a viable option?

To summarize this study, the researcher set out to determine if alternate transport could serve as a viable means of providing health care service to Norfolk citizens who call 911 for service. Two questions were reviewed in depth:

*1) Can a paramedic respond to a 911 call, accurately triage (assess) the patient, and then, properly refer them to alternative transport?*

*2) Were there any adverse impact due to Alternative Transport?*

This Alternate Transport Study is a smaller subset of a larger study being conducted by Eastern Virginia Medical School. This researcher has been working as a member of that research team in collecting, collating, and analyzing the data. The design for this study required obtaining observation data and then reviewing the data collection forms to obtain the data relevant to alternate transport and adverse impact. The data was

then analyzed aggregating it and classifying it into subcategories that allowed the researcher to answer the questions.

The results of the study indicate clearly that there are no adverse impacts to using the alternate transport method of taxi cabs in lieu of an ambulance for emergent cases. In fact, 8.7% of the patients were improperly assigned to non emergent transportation and no adverse impact occurred. This does not mean to say that alternate transport should be used for emergent patients but only that in those few cases where an improper assignment of a patient occurred, the transport method did not have an adverse impact on the patient's health.

The results of the study did not unequivocally support the contention that paramedics could appropriately assign patients to the correct transport method. As noted, they did not do so 8.7% of the time. However, 91.3% of the patients were assigned correctly and would seem to indicate that the alternate transport method may have merit and should be further evaluated for consideration.

## Appendix A

Continuing Review Report or Notification of Closure Form

Eastern Virginia Medical School (EVMS) Institutional Review Boards FWA 00003956

512 Fairfax Hall, 721 Fairfax Avenue, Norfolk, VA 23507

Amendments should be submitted separately from the Continuing Review process

The total number of participants enrolled in this study at this site since the study was initiated is 27

This Continuing Review Report is for the time interval of: 05 / 19 / 05 to 2 / 01 / 06

**RENEW:** For continuing enrollment of new subjects

**RENEW:** Enrollment closed on the following date:  / /

**TERMINATE (CLOSE OUT):** Effective on the following date:  / /  
 Instructions: Submit 2 copies of this completed form (Abstract not required)

IRB Number: 05-03-FB-0055	Date Submitted: 2/07/06
Complete Project Title: Emergency Medical Services Alternative Transport Project	
Principal Investigator ( <i>1 name only</i> ) Barry Knapp M.D. FACEP Principal Investigator's EVMS Department (if appropriate): Emergency Medicine	Status: <input type="checkbox"/> EVMS-Salaried <input checked="" type="checkbox"/> EVMS-Non-salaried <input type="checkbox"/> Trainee
Complete Address: 600 Gresham Drive Norfolk, VA 23507	Phone Number: 757-388-3897
Email Address (required): loriandbar@aol.com	Fax Number: 757-622-6344
If Applicable, list each co-investigator ( <i>and include each co-investigator's address, EVMS academic department (if appropriate), and HIPAA training completed</i> ): Johnathan Sheele M.D. EVMS Emergency Medicine, 600 Gresham Dr. Jennifer Prince RN, MS (Sentara Norfolk General Hospital)	
Person Completing this Application: Jennifer Prince RN, MS	Status: <input type="checkbox"/> Research Staff <input checked="" type="checkbox"/> Study Coordinator <input type="checkbox"/> Other
Complete Address: 600 Gresham Dr. Norfolk, VA 23507	Phone Number: 757-388-5967
Email Address (required): jlprince@sentara.com	Fax Number: 757-622-6344
Sponsor: Tidewater Emergency Medical Council (TEMS)	

1. Type of review requested for this continuing review for the period specified above:

<p>Subjects still actively receiving treatment, undergoing study procedures, or the <b>Sponsor</b> requires <b>full (convened) Board review</b> of this continuing review:</p> <p>✓ <b>Please submit the following:</b></p> <ul style="list-style-type: none"> <li>▪ This form with original signatures on one form and 2 current unstamped copies of each consent form.</li> <li>▪ No consent forms are required if the study is closed to subject entry.</li> <li>▪ 20 stapled packets, each containing this form, abstract, and current unstamped consent form(s). Consent forms are required <b>ONLY</b> if the study is still open to subject entry.</li> <li>▪ 2 copies of your latest approved protocol with changes made during the period specified above identified.</li> </ul> <p><i>[Active = participant was still receiving drug, device, agent or ongoing monitoring other than telephone questions or like means.]</i></p>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<p>No active subjects, no subjects enrolled, or <b>ONLY</b> data analysis taking place:</p> <p>✓ <b>Please submit the following:</b></p> <ul style="list-style-type: none"> <li>▪ Two copies of this form with original signatures on one form and 2 current unstamped copies of each consent form if the study is still open to subject enrollment.</li> <li>▪ No consent forms are required if the study is closed to subject entry.</li> <li>▪ 1 copy of your latest approved protocol with changes made during the period specified above identified.</li> </ul>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

## 2. Documentation of training:

<p>It is necessary for all investigators and co-investigators to complete human subject's protection training in order to receive IRB approval to proceed with research using human subjects, their data, or biological samples. Training opportunities and requirements can be found on the Office of Research web site at <a href="http://www.evms.edu/research/office/irb.html#Required Training">http://www.evms.edu/research/office/irb.html#Required Training</a>.</p>	
<input checked="" type="checkbox"/>	<p>I have completed human subjects protection training and my verification is on file with the EVMS Office of Research.</p>
<input type="checkbox"/>	<p>Enclosed is my certificate verifying that I have completed human subjects protection training.</p>
<input checked="" type="checkbox"/>	<p>All co-investigators have completed human subject's protection training and their verification is on file with the EVMS Office of Research.</p>
<input type="checkbox"/>	<p>Enclosed are certificates verifying that all co-investigators have completed human subjects protection training.</p>
<input checked="" type="checkbox"/>	<p>I completed HIPAA training for <b>research investigators</b> on <u>  12  /  2004  </u>. Type of training was:</p> <p style="padding-left: 40px;"> <input checked="" type="checkbox"/> EVMS HIPAA "For Whose Eyes Only?"    <input type="checkbox"/> NIH HIPAA training  <input type="checkbox"/> Presentation by Trainer    <input type="checkbox"/> Read appropriate training materials </p>
<input type="checkbox"/>	<p>All co-investigators have completed HIPAA training and the type of training is indicated on the co-investigator listing submitted as part of this Application.</p>
<p>Please note that Bloodborne Pathogen Training is mandated annually for <b>EVMS faculty and staff</b> with potential exposure to blood/body fluid by the Occupational Safety and Health Administration (OSHA). Contact the Occupational Health Department at 446-5870 for information on training dates for you and your staff.</p> <p>✓ Will you/your staff be working with blood/body fluids? <input checked="" type="checkbox"/> No    <input type="checkbox"/> Yes</p> <p>✓ The date of my last Bloodborne Pathogen Training is <u>  /  /  </u></p>	

## 3. Financial statement:

Have you, other family member or any other person responsible for the design, conduct, or reporting of this research received from the sponsor (or a subsidiary or parent company of the sponsor):

<p>Salary, other payments for services (e.g., consulting fees or honoraria), recruitment bonuses, trips, referral fees or other incentives?</p>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
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Equity interests (e.g., stocks, stock options, or other ownership interests greater than 5% ownership or greater than \$10,000 per annum of salary, fees, or other continuing payments)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Intellectual property rights (e.g., patents, copyrights and royalties from such rights)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If "yes," to any of the above, please provide a written explanation of the situation.

<input checked="" type="checkbox"/> Bon Secours DePaul Medical Center	<input type="checkbox"/> Bon Secours Mary view Hospital	<input type="checkbox"/> Children's Hospital of The King's Daughters
<input type="checkbox"/> Children's Specialty Group/Monarch	<input type="checkbox"/> Devine Tidewater Urology	<input type="checkbox"/> Eastern Virginia Medical School
<input type="checkbox"/> Sentara Bayside Hospital	<input type="checkbox"/> Sentara CarePlex Hospital	<input checked="" type="checkbox"/> Sentara Leigh Memorial Hospital
<input checked="" type="checkbox"/> Sentara Norfolk General Hospital	<input type="checkbox"/> Shore Health Services	<input type="checkbox"/> Virginia Oncology Associates
<input type="checkbox"/> Other local site (specify, including complete address):		

4. **This study is active at the following local sites:**

Is this study also conducted at any national or international sites (not listed above)?

No       Yes

5. **Type of activity that took place at the local site(s) during the reporting period:**

Investigational Drugs/Biologics: IND#:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Investigational Devices: IDE#:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Humanitarian Device Exemption: #	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

6. **Types of participants: (check all that apply)**

<input type="checkbox"/> Children (specify age range):	<input checked="" type="checkbox"/> Adults (specify age range): 18-65	
<input type="checkbox"/> Students/Employees	<input type="checkbox"/> Healthy Volunteers	<input type="checkbox"/> Critically Ill Patients
<input type="checkbox"/> Cognitively Impaired Individuals	<input type="checkbox"/> Subjects in Emergency Conditions	<input type="checkbox"/> Economically Vulnerable Subjects
<input type="checkbox"/> Pregnant Women	<input type="checkbox"/> Fetus(es)	<input type="checkbox"/> In vitro fertilization
<input type="checkbox"/> Other: (specify):		

7. **Summary of local participant's status during this reporting period (or at close-out):**

Participant's Status	RESPONSE
<b>(NOTE: a participant may be listed in more than one category)</b>	
During this reporting period, were any participants enrolled? 27	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
At any time during this reporting period, how many participants were active on the trial? <i>[Active = participant was still receiving drug, device, agent or ongoing monitoring other than telephone questions or like means. NOTE: an active participant could have been enrolled in an earlier reporting period.]</i>	0
During this reporting period, how many participants were on follow-up <u>ONLY</u> ?	0
During this reporting period, how many participants completed the study?	27
During this reporting period, how many participants were withdrawn at their request?	0
▪ Reason(s) for withdrawal:	

During this reporting period, how many participants were withdrawn at the request of the PI? ▪ Reason(s) for withdrawal:	0
During this reporting period, how many participants died due to the progression of disease?	0

8. Summary of participant's ethnicity/race and gender during the reporting period (or at close-out):

Data not aggregated by ethnicity/race and/or gender.

ETHNICITY/RACE	MALE	FEMALE	TOTAL
Hispanic or Latino			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other/Unknown			
Total			

Is the enrollment by gender and ethnicity/race in line with what was expected?  Yes  
 No If "no," please explain why.

9. Summary of participant's unanticipated problems involving risks to subjects or others, or adverse events during the reporting period (or at close-out):

<input checked="" type="checkbox"/>	There were no unanticipated problems or adverse events during this reporting period.
<input type="checkbox"/>	The enclosed IRB-generated list, compiled from reports submitted by the investigator, accurately represents the unanticipated problems and adverse events reported during this reporting period. <input type="checkbox"/> No changes or corrections are necessary <input type="checkbox"/> A list, including changes and/or corrections, is enclosed
<input type="checkbox"/>	This is a close-out report; no additions, changes or corrections are being reported

10. Does this study include safety monitoring?

Local data and safety monitoring plan in place	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Sponsor reviews adverse events, interim findings and relevant literature	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Data (Safety) Monitoring Board [D(S)MB], Data Monitoring Committee (DMC) or other similar body in place. <i>If "Yes," please include a copy of the latest report issued with this report.</i>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

11. Were there any changes in risk/benefit relationship?

Has the risk/benefit relationship changed as a result of any new information or performance of the study? <i>[If "Yes", please provide a brief explanation including how adverse events, protocol modifications, and results from other studies affect the risk/benefit relationship.]</i> • If "Yes," how has this new information changed the risk/benefit ratio as reflected in the consent form? • If "Yes," how was this information shared with participants?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
---	------------------------------	--



**12. Were any complaints received about the research?**

<i>[If "Yes," please provide a brief explanation including the nature of the complaint, your response, and whether the conduct of the trial was changed in any way.]</i>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
--	------------------------------	--

**13. Attached documents:**

Summary of results:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Copies of publications or presentations:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Relevant information from other studies:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

**14. Investigator's statement:**

Waiver of consent was granted for this study	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Waiver of consent for the use of protected health information (PHI) was granted for this study	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
An approved consent form has been signed for each subject entered in this study. A copy of the signed form was given to each subject and the original is on file.	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Principal Investigator Signature: _____	Date: _____ / _____ / _____ M/ D/ Y	

\*\*\*\*\* IRB USE ONLY \*\*\*\*\*

**FINAL DISPOSITION:**

REVIEW CATEGORY	ACTION	IS RE-CONSENT NEEDED?	CONTINUING REVIEW DEADLINE
<input type="checkbox"/> Expedited	<input type="checkbox"/> Approved	<input type="checkbox"/> Yes	Date: ___ / ___ / ___ M/ D/ Y
<input type="checkbox"/> Full (Convened Board)	<input type="checkbox"/> Disapproved	<input type="checkbox"/> No	
	<input type="checkbox"/> Study Closed		
Signature: _____			Date: ___ / ___ / ___ M/ D/ Y
IRB CHAIR (OR OTHER APPROVED) SIGNATURE			
SIGNED BY: <input type="checkbox"/> IRB CHAIR <input type="checkbox"/> IRB VICE CHAIR <input type="checkbox"/> IRB MANAGER			

Application for Approval of Research Involving Human Subjects

Eastern Virginia Medical School (EVMS) Institutional Review Board

Continuing Review Abstract

*Do Not Exceed Two(2) Pages and Do Not Include Extra Pages*

**IRB Number: 05-03-FB-0055**

**Complete Project Title: Emergency Medical Services Alternative Transport Project**

**Principal Investigator: Barry Knapp**

Emergency Medical Services (EMS) are often utilized to transport patients to the Emergency Department (ED) for medical complaints that are not life threatening. Inappropriate use of EMS can increase ambulance response times and delay care to the critically ill population potentially leading to higher mortality rates. The purpose of this study is to provide an alternative method of transportation to the ED for patients with minor medical problems. An alternative method of transport will ensure medical care in a timely fashion while minimizing the use of EMS resources.

**1. PURPOSE OF THE STUDY:**

**2. BRIEF DESCRIPTION OF DESIGN:**

This is a multi-center non-randomized study to be performed in the City of Norfolk. Emergency response is activated by dialing 911 in the City of Norfolk. EMS ambulance is then dispatched. EMS arrives via ambulance at scene and performs a standard evaluation that includes vital signs, history, and physical exam. If person does not meet any exclusion criteria, voluntary participation and written consent will be obtained. A taxicab voucher will be given to patient and EMS personnel will call the cab company. Patients will surrender voucher upon entering the vehicle and the cab company will transport patient to the closest ED.

**3. PARTICIPANT INFORMATION:**

Duration of individual subject's involvement: Assessment and transportation time, approximately one hour.

How are subjects recruited? Activation of EMS for ambulance transportation

**Exclusions: Exclusions:**

\*Age less than 18 years or greater than 65

**\*Abnormal vital signs**

\*Pulse greater than 110 or less than 50 beats per minute

\*Systolic blood pressure less than 90mm Hg or greater than 190mm Hg

\*Diastolic blood pressure greater than 115 mm Hg

\*Pulse Oximetry less than 94%

\*Respiratory rate of less than 12 or greater than 24 breaths per minute

\*Temperature greater than 101 Fahrenheit by history

\*chest discomfort/syncope

\*dyspnea or shortness of breath

\*abdominal or pelvic pain

\*pregnancy related complaints

\*multi-system trauma

\*uncontrolled hemorrhage

\*gastrointestinal complaints (vomiting, diarrhea, abdominal pain)

\*Glasgow Coma Scale <15

\*Confusion including seizure or postictal

\*Psychiatric patients (including suicidal/homicidal, psychosis, overdose)

\*Headache

\*Intoxication

\*abuse or neglect of an adult

\*any patient scenario where the crews best judgment dictates transport

Examples: language barrier, non-ambulatory, risk of physical harm

Inducements: None

**4. BENEFITS TO SUBJECTS:**

Transportation fee waived. May decrease ambulance response times to overall population.

**5. RISKS TO SUBJECTS:**

Potential worsening of subject's medical condition. Delay in arriving in the Emergency department.

**6. MEASURES TO MINIMIZE RISKS:**

Formal agreement with local taxi company to assist with transportation to the ED within an hour of notification by EMS personnel. PHI will be protected according to HIPPA guidelines. If at any time patient complaint or condition changes they are encouraged to re-contact EMS via 911.

**7. SUMMARIZE ALL CHANGES TO THE STUDY (INCLUDING CHANGES TO THE CONSENT FORM[S]) DURING THE REPORTING PERIOD:**

1. Removed Jim Powers as a Co-investigator, Added Johnathan Sheele and Jennifer Prince as Co-Investigators.
2. Clarification of two exclusion criteria: Headache and Psychiatric illness.
3. The study team reviewed preliminary data. Thus far there has not been any inpatient hospital admissions out of the study population.

## Appendix B

### UNIVERSITY OF RICHMOND INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF RESEARCH PARTICIPANTS NOTICE OF ACTION

Date: 4/24/06

Name(s): Nicholas Nelson

Faculty  Student  Other

Faculty Mentor: M. Gibson

Is this for a class?  Yes  no

If yes, department and course number HRM

Project Title: Alternative Transport Study in the City of Norfolk

The IRB has reviewed your research protocol by  full review  expedited review.

Your application is:

- Exempt from further review Your project does not fall within federal or university guidelines requiring review. If the nature of the project changes, you must resubmit this project for further review.
- Approved Please review the criteria for approval at the end of this form.
- Approved with conditions Please respond via email to the Chair of the IRB how you plan to address the concerns outlined at the end of this form.
- Third party verification required.
- Disapproved The IRB has some concerns regarding your proposed research; therefore, your project cannot be approved at this time. Please contact the Chair of the IRB to discuss the issues outlined at the end of this form.
- Incomplete A decision on your protocol has been temporarily withheld until the information listed at the end of this form is provided for IRB consideration. Please send this information to the Chair of the IRB via email.

.....

Kathy Hoke  
Kathy Hoke, Chair  
Institutional Review Board (8089)

4/24/06  
Date

Notes: Approved by Eastern Virginia Medical School IRB #05-03-FB-0055; principal investigator here

Final Approval Kathy Hoke 4/24/06

### Conditions of Approval

If your project has been **approved** by the University of Richmond Institutional Review Board for the Protection of Human Participants (IRB), this approval is based upon the conditions listed below. It is your responsibility to ensure that your research adheres to these guidelines.

1. IRB approval is for a period of one year. If this research project extends beyond one year, a request for renewal of approval (<http://as.richmond.edu/facstaff/irbresources.htm>) must be filed.
2. All subjects must receive a copy of the **approved** informed consent form. Unless a waiver of signature was given, researchers must keep copies of informed consent forms on file for three years.
3. Any substantive changes in the research project must be reported to the chair of the IRB. Changes shall not be initiated with IRB approval except where necessary to eliminate apparent immediate hazards to the subject. Based on the proposed changes, a new review may be necessary.
4. Any adverse reaction or other complication of the research which involves real or potential risk or injury to the subject must be reported to the Chair of the IRB immediately.

If your project has been **approved with conditions** or **disapproved**, or if your protocol is **incomplete**, please respond to the following concerns/questions of the IRB. Please send revisions or additional information to the Chair via email.

## Appendix C

### *Subject Consent Form*

Eastern Virginia Medical School (EVMS) Institutional Review Board

## STUDY TITLE

Emergency Medical Services Alternative Transport Project

## PRINCIPAL INVESTIGATOR

Barry Knapp M.D. FACEP (EVMS Dept. of Emergency Medicine)

## CO-INVESTIGATOR

Johnathan Sheele M.D. (EVMS Dept. of Emergency Medicine)  
Jennifer Prince RN, MS (Sentara Norfolk General Hospital)

## SPONSOR

This study is being sponsored by Tidewater Emergency Medical Council to assist with alternative and administrative costs. The investigators are not being financially compensated.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to provide an alternative (choice) method of transportation for patients with minor medical problems to be transported to the Emergency Department in a timely fashion while minimizing the use of Emergency Medical Services (EMS) resources.

## WHY ARE YOU BEING ASKED TO TAKE PART?

You are being asked to participate in this research project because you have a minor complaint or medical condition that is not life threatening. We are proposing alternative transportation to the hospital for these cases.

This is a research study. This study includes only people who choose to take part. Please take your time to make your decision and feel free to ask any questions you might have.

If you refuse to participate you will be transported in an ambulance to the nearest Emergency Department as outlined in the City of Norfolk's EMS Standard Operating protocol.

## WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?

At this local site about 200 people will take part in this study. This study is expected to enroll subjects for a one year period starting in the spring 2005.

## WHEN SHOULD YOU NOT TAKE PART?

If you have any of the following conditions listed below, you should **not** take part in this study:

- Age less than 18 years or greater than 65 years
- Abnormal vital signs
  - Heart rate greater than 110 or less than 50 beats per minute
  - Extremely high blood pressure (as measured by the paramedics)
  - Oxygen levels (as measured by the paramedics) in the blood are low
  - Breathing rate of less than 12 or greater than 24 breaths per minute

Temperature greater than 101 Fahrenheit reported by you

- Allergic reaction
- Chest pain
- Shortness of breath
- Stroke symptoms including weakness, numbness and double vision
- Abdominal or pelvic pain
- Pregnancy related complaints
- Trauma patients
- Uncontrolled bleeding (to include minor bleeding in hemophiliacs)
- Vomiting and diarrhea
- Loss of consciousness
- Psychiatric problems or complaints (with illness being primary complaint)
- Seizures including post-ictal state
- Dizziness
- Overdose
- Headache (as a primary complaint)



- Suicide attempt
- Confusion, including dementia, drug and alcohol intoxication.
- Abused, neglected or cannot walk

There may be other reasons why you may not be able to participate in this study. EMS personnel, the study doctor, or staff will discuss these with you.

## **WHAT IS INVOLVED IN THIS STUDY?**

First, the ambulance crew will identify you as a potential participant. Per EMS standard of care, you will be evaluated by an Advance Life Support provider. Vital signs including pulse, blood pressure, and breathing rate will be performed as well as a history and physical exam.

After an initial evaluation by EMS personnel, you will be offered the opportunity to participate in this study if you are medically stable and do not meet any of the above criteria. If you agree to participate in this study a transportation voucher will be given to you and the EMS crew will notify the Taxicab Company to transfer you to the nearest Emergency Department. You may also choose to contact the Taxicab companies yourself:

Black and White cabs: 855-4444 or Norfolk Checker Taxi: 855-6611.

Your taxi voucher will be honored only on the day it is issued and is only valid for a one-way trip to the Emergency Department. You will need to make your own arrangements to get home. You will need to surrender the transport voucher upon entering the taxi.

By agreeing to participate, you acknowledge that the Taxi companies do not and will not provide any kind of medical care. If you are concerned or your condition/complaints change at anytime, please notify the taxi driver who can dial 911 to request an ambulance.

Though your complaint or medical problem may not need emergent ambulance transport; you do need to be evaluated by a physician in a timely manner.

If at any time your complaint changes or condition worsens, you may re-activate EMS by dialing 911.

## **WHAT ARE THE RISKS OF THE STUDY?**

Participation in this study does have some risk. Delay in getting to the Emergency department and worsening of your medical condition are possibilities.

A risk associated with allowing your data to be saved is the release of personal information from your study record. We will strive to protect your records so that your personal information (like name, address, social security number and phone number) will remain private.

There also may be other risks that are unknown and we cannot predict.

## **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to taking part in this study, there may or may not be direct benefit to you. If you are a candidate for alternative transportation, you will not be charged an ambulance transportation fee to the hospital and taxi transportation to the hospital will be provided without cost to you. There is no guarantee that you will personally benefit from taking part in this study however we hope the information learned from this study will benefit other people who will need use the EMS services in the future and decrease emergent ambulance transport times.

## **WHAT OTHER OPTIONS DO YOU HAVE?**

Instead of being in this study, you have these options:

- You can be transported to the nearest Emergency Department via ambulance transport
- You may choose not to participate in this research study.

## **WHAT ABOUT CONFIDENTIALITY?**

In conducting this research study, it may be necessary for the research team to send information about you and your health to persons in other organizations. For example, Dr. Knapp or members of his research team will report the results of your study-related activity to Tidewater Emergency Medical Council (TEMS), the sponsor of the study. This information may include what we call “protected health information (PHI),” which includes personal information about you. It will be shared with others only as described below:

Description of Your PHI to Be Disclosed	Organization and Person (or their title) Disclosing Your PHI	Organization and Person (or their title) Receiving Your PHI	Purpose of Disclosure
Age, gender, history and physical, admission and discharge summaries	Dr. Barry Knapp, Dr. John Sheele Eastern Virginia Medical School, and Jennifer Prince RN (Sentara)	Tidewater Emergency Council	To evaluate appropriate use of the EMS

All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be disclosed if required by law. Once your protected health information is disclosed for research, such as to the sponsor, federal privacy laws may no longer protect the information.

- If you refuse to give your approval for your personal information to be shared as described in this consent form, you will not be able to be in this study. However, your choice will not affect any medical benefits to which you are entitled.
- By signing this consent form to participate in the study, you are allowing the research team to share PHI, as described in this consent form.
- You have the right to cancel your approval for the sharing of PHI. If you cancel your approval, you will have to leave the study. All information collected about you before the date you cancelled will continue to be used. To cancel your approval, you must notify Dr. Barry Knapp in writing at Sentara Norfolk General Hospital, 600 Gresham Drive, Raleigh Building, Rm 304, Norfolk VA 23507.
- Your approval for the sharing of personal information about you for this study expires at the end of the study.
- You also have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.
- Any research information in your medical record will become a permanent part of that document.

Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. Reviewers may include, for example, an Eastern Virginia Medical School Institutional Review Board, Federal Food and Drug Administration (FDA) the Office for Human Research Protection (OHRP), and sponsor.

Information learned from this research may be used in reports, presentations and publications. None of these will personally identify you.

## **WHAT WILL PARTICIPATION IN THE STUDY COST OR PAY?**

There are no additional costs to you associated with taking part in this study.

## **WHAT IF I GET INJURED?**

In the case of injury or illness resulting from this study, emergency medical treatment is available and will be provided by Sentara Norfolk General Hospital and paid for by your insurance company. Further medical care and/or hospitalization resulting from this injury or illness you and/or your insurance company will be charged.

Eastern Virginia Medical School and Sentara Norfolk General Hospital will not provide free medical care for any sickness or injury resulting from being in this study. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, you do not waive any legal rights by signing this consent form.

## **WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time. If you do leave the study, discuss it with the investigator who will help you do so in the safest way. If you leave, the study it will not result in any penalty or loss of benefits to you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Virginia law says that if you or anyone associated with the study is exposed to the other person's body fluids that might transmit the virus that causes AIDS or the Hepatitis B or C virus:

- The person whose body fluids were involved is deemed to have consented to testing for those viruses so that no further consent is necessary to test the person for these diseases and
- Those test results will be released to the person who was exposed.

## WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the investigator, Dr. Barry Knapp, at 757-388-3397 or call the Emergency Department at 757-388-3296.

For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Barry Knapp at 757-388-3397. You may also contact Dr. Robert Williams, an employee of Eastern Virginia Medical School, at (757) 446-8423.

<b>SIGNATURE</b>			
You will get a copy of this signed form. You may also request information from the investigator. By signing your name on the line below, you agree to take part in this study and accept the risks.			
_____ Signature of Participant	_____ Typed or Printed Name	_____ Participant	____/____/____ MM/ DD/ YY
_____ Signature of Witness <input type="checkbox"/> Witnessed Signature Only <input type="checkbox"/> Witnessed Consent Process	_____ Typed or Printed Name		____/____/____ MM/ DD/ YY
<b>STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE</b>			
I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.			
_____ Signature of Investigator or Approved Designee			____/____/____ MM/ DD/ YY

APPENDIX D

092

EMS Alternative Transport  
Taxi Voucher

Date: \_\_\_\_\_

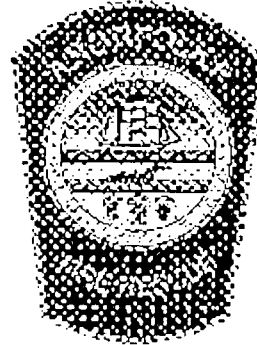
Subject Name: \_\_\_\_\_

Social Security #: \_\_\_\_\_

EMS Run Number: \_\_\_\_\_

Medic #: \_\_\_\_\_

Time Taxi Requested: \_\_\_\_\_



Refused Alternative Transport

\_\_\_\_\_  
Paramedic Signature

(Do not detach)

.....  
Taxi Pick-up Time: \_\_\_\_\_

Hospital Transported to (circle):

Norfolk General

Leigh

Depaul

Hospital Arrival Time: \_\_\_\_\_

\_\_\_\_\_  
Taxi Driver Signature

**Black and White cabs: 855-4444 or Norfolk Checker Taxi: 855-6611**

## Appendix E

### Criteria for Inclusion in Study:

**Table A-1: Reasons for Improper Enrollment**

Age less than 18 years or greater than 65 years
Abnormal vital signs
Heart rate greater than 110 or less than 50 beats per minute
Extremely high blood pressure (as measured by the paramedics)
Oxygen levels (as measured by the paramedics) in the blood are low
Breathing rate of less than 12 or greater than 24 breaths per minute
Temperature greater than 101 Fahrenheit reported by you
Allergic reaction
Chest pain
Shortness of breath
Stroke symptoms including weakness, numbness and double vision
Abdominal or pelvic pain
Pregnancy related complaints
Trauma patients
Uncontrolled bleeding (to include minor bleeding in hemophiliacs)
Vomiting and diarrhea
Loss of consciousness
Psychiatric problems or complaints (with illness being primary complaint)
Seizures including post-ictal state
Dizziness
Overdose
Headache (as a primary complaint)
Suicide attempt
Confusion, including dementia, drug and alcohol intoxication.
Abused, neglected or cannot walk

## Appendix F

### Triage Enrollment Data

The data provided in the Table A-2: Triage Enrollment Data is a compilation by Voucher number of patients that were properly or improperly enrolled and whether there was an adverse impact as a result. As can be seen from the data, Item Numbers 15, 17, 25, 35, 54, 68, 69, 84 and 93 were improperly enrolled. The reasons for this are: patients age and chief complaint are not appropriate for inclusion in this study.

**Table A-2: Reasons for Improper Enrollment**

<b>Item Number</b>	<b>Voucher</b>	<b>Properly Enrolled</b>	<b>Adverse event</b>
1.	7	TRUE	No
2.	196	TRUE	No
3.	122	TRUE	No
4.	84	TRUE	No
5.	183	TRUE	No
6.	217	TRUE	No
7.	35	TRUE	No
8.	213	TRUE	No
9.	202	TRUE	No
10.	228	TRUE	No
11.	10	TRUE	No
12.	201	TRUE	No
13.	9	TRUE	No
14.	115	TRUE	No
15.	200	<b>FALSE</b>	No
16.	116	TRUE	No
17.	182	<b>FALSE</b>	No
18.	180	TRUE	No
19.	234	TRUE	No
20.	43	TRUE	No
21.	95	TRUE	No
22.	197	TRUE	No
23.	192	TRUE	No
24.	17	TRUE	No
25.	190	<b>FALSE</b>	No
26.	174	TRUE	No
27.	121	TRUE	No
28.	3	TRUE	No



Item Number	Voucher	Properly Enrolled	Adverse event
29.	93	TRUE	No
30.	15	TRUE	No
31.	8	TRUE	No
32.	94	TRUE	No
33.	21	TRUE	No
34.	26	TRUE	No
35.	38	<i>FALSE</i>	No
36.	114	TRUE	No
37.	175	TRUE	No
38.	206	TRUE	No
39.	124	TRUE	No
40.	235	TRUE	No
41.	125	TRUE	No
42.	4	TRUE	No
43.	16	TRUE	No
44.	18	TRUE	No
45.	85	TRUE	No
46.	173	TRUE	No
47.	70	TRUE	No
48.	205	TRUE	No
49.	64	TRUE	No
50.	5	TRUE	No
51.	208	TRUE	No
52.	69	TRUE	No
53.	176	TRUE	No
54.	86	<i>FALSE</i>	No
55.	210	TRUE	No
56.	227	TRUE	No
57.	181	TRUE	No
58.	63	TRUE	No
59.	203	TRUE	No
60.	117	TRUE	No
61.	123	TRUE	No
62.	178	TRUE	No
63.	120	TRUE	No
64.	179	TRUE	No
65.	88	TRUE	No
66.	191	TRUE	No

Item Number	Voucher	Properly Enrolled	Adverse event
67.	118	TRUE	No
68.	12	<i>FALSE</i>	No
69.	231	<i>FALSE</i>	No
70.	177	TRUE	No
71.	232	TRUE	No
72.	83	TRUE	No
73.	13	TRUE	No
74.	65	TRUE	No
75.	96	TRUE	No
76.	185	TRUE	No
77.	209	TRUE	No
78.	67	TRUE	No
79.	172	TRUE	No
80.	27	TRUE	No
81.	212	TRUE	No
82.	6	TRUE	No
83.	14	TRUE	No
84.	87	<i>FALSE</i>	No
85.	229	TRUE	No
86.	25	TRUE	No
87.	193	TRUE	No
88.	204	<i>TRUE</i>	No
89.	23	TRUE	No
90.	33	TRUE	No
91.	214	TRUE	No
92.	11	TRUE	No
93.	215	<i>FALSE</i>	No
94.	53	TRUE	No
95.	199	TRUE	No
96.	68	TRUE	No
97.	36	TRUE	No
98.	72	TRUE	No
99.	195	TRUE	No
100.	113	TRUE	No
101.	194	TRUE	No
102.	66	TRUE	No
103.	119	TRUE	No

## Appendix G

This table depicts the data on the nine patients enrolled in the study improperly along with the reasons.

**Table A-3 Improper Enrollment Data**

#	Patient No.	Patient Description	Discharged from ED/Hospital Admittance	Reason for Improper Enrollment	Impact
1	182	26-year old black female called 911 for weakness and abdominal pain.	Admitted to the hospital and went to surgery for Acute Jejunal Intersection	The patient was improperly enrolled based on her complaint of abdominal pain	No adverse event attributed to her arrival by Taxi and not EMS
2	190	32-year old black male who called 911 complaining of weakness	He was admitted to the hospital for renal insufficiency, AIDS, N/V failure to thrive, non compliance with meds	The patient was improperly enrolled due to his history of HIV	No adverse event could be attributed to her arrival by taxi and not EMS.
3	38	43-year old black male who called 911 complaining of feeling suicidal.	He was admitted to Virginia Beach Psychiatric for treatment of depression/suicidal and homicidal ideations.	The patient was improperly admitted to the study as he was complaining of suicidal and homicidal ideations.	No adverse event could be attributed to his arrival by taxi and not EMS.
4	26	86-year old white female called 911 complaining of breathing problems.	Discharged from ED	The patient was improperly admitted to the study for multiple reasons, the patients age of 86 was inappropriate, the complaint of breathing problems and finally no EMS vital signs were recorded for this patient	No adverse event could be attributed to her arrival by taxi and not EMS.

#	Patient No.	Patient Description	Discharged from ED/Hospital Admittance	Reason for Improper Enrollment	Impact
5	12	56-year old black male called 911 complaining of arm pain and swelling.	The patient was admitted to the hospital and required surgery to correct a dialysis shunt malfunction.	The patient was improperly admitted based on the patients EMS vital signs.	No adverse event occurred due to the patient arriving via taxi and not EMS.
6	231	61-year old black female called 911 complaining of breathing problems with nausea, vomiting and diarrhea	The patient was admitted to the hospital for treatment of Peritonitis and Hypokalemia.	The patient was improperly admitted to the study based on her, chief complaint of abdominal pain and she was a dialysis patient.	No adverse event could be attributed to her arrival by taxi and not EMS.
7	87	84-year old Unknown female called 911 with no complaints, but her family stated she was weak.	The family stated at ED triage that the elderly female had weakness/fatigue/chest tightness/x 1 month. The patient was discharged from the ED.	The patient was improperly admitted to the study based on her age.	No adverse event could be attributed to her arrival by taxi and not EMS.
8	215	52-year old black male called 911 complaining of arm pain.	The patient was discharged from the ED.	The patient was improperly admitted based on the patient's injury a dislocated shoulder	No adverse event could be attributed to his arrival by taxi and not EMS.
9	200	71- year old black male called 911 complaining of laceration to his toe.	The patient was discharged from the ED after a 2cm Lac to R 4th Toe with suture repair.	The patient was improperly admitted based on the patient's age.	No adverse event could be attributed to his arrival by taxi and not EMS.

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## **Biography**

Nicholas E. Nelson is a Firefighter/Paramedic with Norfolk Fire-Rescue. Mr. Nelson started his career in Fire and EMS in 1981 with the Vienna Volunteer Fire Department (VVFD) in Vienna, WV. During his membership with VVFD he was a firefighter/assigned to the department fire investigation unit and on the department bylaws committee. He continued his career as an EMT dispatcher and paramedic with St. Josephs Hospital Ambulance Service in Parkersburg, WV from 1985 until moving to Norfolk, VA in 2000. Mr. Nelson has spoken at numerous state and local seminars including being a guest speaker at the 1993 World Safety Organizations International Conference in Memphis TN, the 2003 Firehouse Expo, in Baltimore MD, and numerous other state and local seminars. Currently, Mr. Nelson is assigned to Rescue Company 2 in the City of Norfolk. He is a Master Firefighter and Field Training Instructor of new EMS providers as well as students from Tidewater Community College. His assignments include being a member of the departments technical rescue team, assisting with specifications for new fire apparatus, and assisting with training of new fire recruits as a guest instructor for Tidewater Regional Fire Academies.