

Clinical Research Proposal for the Jersey City Medical Center Institutional Review Board

Date of Submission: January 3, 2010

Principal Investigator: Cris Savkov

Investigators: Christina Vassallo, Tara Ryan, Maria Bernardo

Title: Rate of Consent for Tissue Donation in an institution with Emergency Room & ICU Nurses trained as Designated Requestors

Project Description:

The New Jersey Sharing Network will hold a one day “Designated Requestor” training seminar for the nurses from the Emergency Room and the ICU. The one-day session spans 8 hours of lecture and interactive presentation by The Sharing Network staff. Topics to be explored in seminar-style presentations include the following: Centers for Medicare & Medicaid Services Conditions of Participation, The Tissue Process and Referral to Consent, Tissue Recovery and Transplantation, A Donor’s Family Experience, A Recipient’s Experience, Phases of Grief and Objectives of Active Listening, Creating the Proper Environment and Family Interaction (Offering the Opportunity for Donation and Addressing Questions), and Donor Family Support and Services. A look into Jersey City Medical Center’s history and participation in organ donation will also be examined. Nurses will then implement the knowledge and communication skills they learn when broaching the topic of tissue donation with families whose loved ones have passed at Jersey City Medical Center. After one year we will compare the rate of consent from our institution with the rate of consent from St. Joseph's Healthcare System located in Paterson, a comparable institution. During this one year period, the NJ Sharing Network will not hold a Designated Requestor training seminar at that institution.

Objectives:

Our chief objective is to evaluate if the overall rate of consent for donation rises by increasing nurses’ knowledge about the process of tissue donation and therefore enabling them to

effectively answer families' questions. We believe this training seminar will address a gap that exists in nurses' knowledge about tissue donation. We hypothesize that by empowering our nurses with current factual information about tissue donation and the therapeutic communication skills that are necessary to convey this information to families, the number of families who choose to donate will increase. If this hypothesis is correct, we will have verified another method that can be employed to address a critical need. Currently the NJ Sharing Network report that "an estimated 220,000 Americans are treated with transplanted bone and tissue each year". Their work has shown that "one individual who donates after death can provide organs, corneas, skin, bone and tissue for 50 or more people in need" (New Jersey Organ & Tissue Sharing Network).

Methodology:

We will implement a case control analysis to evaluate the effectiveness of the training program. We will compare the data we receive from the Sharing Network on the rate of consent for our institution with the rate of consent during the same time period from St. Joseph's Healthcare System in Paterson. This hospital was selected for comparison due to similar size and comparable demographic population served. In addition, we will also compare our rate of consent with our own previous rates before the training program was initiated. The number of subjects in our study cannot be predetermined due to the nature of the study.

Data Collection:

Our data will be provided by the New Jersey Sharing Network. Currently we receive monthly updates on the number of individuals we refer and the rate of consent. We will continue to use this information that they provide and compare this with data from St. Joseph's Healthcare System.

Appropriateness of methodology:

This methodology is appropriate because we are seeking to measure the amount of change in consent rates after a specific intervention, the Designated Requestor training seminar. St. Joe's will not have this training at their institution therefore the comparison is appropriate.

Appropriateness of Subject Selection:

Due to the nature of our topic, subjects cannot be preselected. Any family member whose loved one has passed at Jersey City Medical Center will be able to benefit from or staff's additional training.

Risks to Research Subjects:

The only risk to those families, to whom we would offer information about donation, would be that some might find it emotionally distressing to talk about. Some families might respond negatively when offered this information. However no family would be forced to learn about or listen to information regarding tissue donation, they would only be offered the opportunity to donate. The Uniform Anatomic Gift Act is a federal law that requires hospitals to ensure that families are offered the option to donate. (Wilson, Reitsma, McKeeown, & Pancoska, 2000). We comply with this federal regulation by contacting the sharing network following any death or once a patient has met a set of clinical criteria that deems death to be imminent. The sharing network then contacts the family of any individual who is a potential donor; either by phone if the patient has already passed or in person if the patient remains on life support. These families are then offered information about donation by the Sharing Network. Therefore our program would not introduce any new potential for harm. Law dictates that they be offered this information, the only difference is which individual first approaches the family.

Consent:

We will obtain consent from St. Joseph's Healthcare System to use their consent rate data that is logged with the New Jersey Sharing Network. We will not need consent to offer donation information to families. As previously mentioned current law dictates that families are offered this information. By ensuring that nurses are fully informed on the subject, we will be able to provide accurate information during a time sensitive process.

Compensation if harmed:

There is no physical or permanent psychological harm that can come from offering individuals more information about tissue donation. In fact, studies have shown that families feel more at ease with the discussion when it is initiated by a trained and knowledgeable individual. This is one reason why organizations like the New Jersey Sharing Network exist in order to ensure that families were approached by knowledgeable staff.

Costs:

The New Jersey Sharing Network is providing the Designated Requestor training seminar free of cost. Our only projected cost would be the possible use of professionals for statistical analysis of the data.

Expected Results:

We expect that by increasing the overall knowledge of our staff and creating an environment where family members can have their questions answered about this process in a timely and sympathetic nature we will greatly increase the rate of consent from our institution.

Proposed Consent Form:

No consent form will be necessary

Department Chair/SVP Approval Statement

Principal Investigator: Cris Savkov

Department: Emergency Department

Protocol Title: Rate of Consent for Tissue Donation in an institution with Emergency Room
 & ICU Nurses trained as Designated Requestors

Amount of Funds Allocated/Requested

Summary of Research Project

The New Jersey Sharing Network will hold a one day “Designated Requestor” training seminar for the nurses from the Emergency Room and the ICU. Nurses will then implement the knowledge and communication skills they learn when broaching the topic of tissue donation with families who loved ones have passed at Jersey City Medical Center. After one year we will compare the rate of consent from our institution with the rate of consent from St. Joseph's Healthcare System, a comparable institution.

Approved Budget

Approvals:

Division Chief (if applicable)

Date

Department Chair or Senior Vice President

Date

IRB Reports:

A report will be submitted to the IRB annually, or more often if required by applicable State, Federal, and local laws and/or applicable Jersey City Medical Center rules, regulations, and requirements.

Investigator Credentials:

Principal Investigator: Cris Savkov, BSN, RN
Jersey City Medical Center, Emergency Department
Nurse Educator

Co-Investigator: Christina Vassallo, BSN, RN
Jersey City Medical Center, Emergency Department
Staff Nurse

Tara Ryan, BSN, RN
Jersey City Medical Center, Emergency Department
Staff Nurse

Maria Bernardo, BSN, RN
Jersey City Medical Center, Emergency Department
Staff Nurse

Advisor: Dr. Susan Salmond EdD, RN

All above investigators are employed by Jersey City Medical Center. There are no possible conflicts of interest identified.

NJ Sharing Network: Zadith E. Colón, MPH CPTC
Hospital Services Manager

Notification:

Individuals and Institutions to be notified if the proposal is approved by the IRB, requires modification or is not approved:

Rita Smith
Chief Nursing Officer
Jersey City Medical Center
355 Grand Street
Jersey City NJ, 07302

Assurance Training Certificate: Please see attached certificates.

References

New Jersey Organ & Tissue Sharing Network. (n.d.). *NJ Sharing Network- Why the Need?*
Retrieved January 05, 2010, from NJ Sharing Network:
<http://www.sharenj.org/understanding%20donation/why%20the%20need.htm>

Wilson, D., Reitsma, W., McKeeown, G., & Pancoska, C. (2000). The Sharing Network: The First Decade. *New Jersey Medicine* , 41-45.

Appendix A- Training Day Itinerary

Jersey City Medical Center Designated Requestor Training February 2010

8:00 – 8:30am	Registration and Continental Breakfast
8:30 – 8:40am	Welcome and Objectives
8:40 – 9:00 am	CMS Conditions of Participation/Data Presentation <i>Zadith Colon, Hospital Services Manager</i>
8:45 – 9:15am	The Tissue Process: Referral to Consent
9:15 – 9:45am	Tissue Recovery & Transplantation
9:45 – 10:00am	Break
10:00 – 10:30am	A Donor Family's Experience <i>TBD</i>
10:30 – 11:00am	A Recipient's Experience <i>TBD</i>
11:30 - 11:45am	JCMC experience/Feedback
11:45 - 12:45pm	Lunch
	Video - Dennis John Tribute
1:00 – 1:20pm	Introduction, Phases of Grief & Objectives of Active Listening <i>Speaker TBD</i>
1:20 - 2:00pm	Creating the Proper Environment, Family Interaction: Offering the Opportunity for Donation & Addressing Questions <i>Bob Sosnicki, Transplant Coordinator RN, BSN, CCRN, CPTC</i>
1:50 – 2:10pm	Donor Family Support & Services <i>Mary Ellen McGlynn, RN, BSN, CPTC</i>
2:15—2:25pm	Break
2:30 – 3:15pm	Role playing – Best practices (3 scenarios)
3:30– 4:15pm	Conclusion of Program & Certificate Presentation