

The Truth About Tissue Donation

Purpose and Objectives

The purpose of this course is to provide participants with basic information regarding the tissue donation process, facts about tissue donation and transplant applications. This course is for one (1) contact hour.

After successful completion of this continuing education course the learner will:

1. Have an increased understanding of tissue donation including:
 - a. The history of tissue transplantation
 - b. The types of tissues that can be donated
 - c. The applications of donated tissues.
2. Have answers to commonly asked questions regarding tissue donation including:
 - a. Myths and misconceptions
 - b. Religious views
3. Describe current Florida legislation governing tissue donation and the Conditions of Participation for Hospitals
4. Describe the FDA oversight of tissue donation and the role of the American Association of Tissue Banks
5. Describe importance of tissue for research and education

Introduction

Every year the gift of tissue donation enhances the lives of hundreds of thousands of tissue transplant recipients. The gift from a single donor can touch the lives of 60 or more people. Bone and soft tissue transplants help repair defects, eliminate or reduce pain, and promote faster healing. For many tissue recipients, donation has helped them recover from debilitating illnesses and lead normal lives.

Hospitals must have in place policies and procedures that ensure that all deaths are reported to the organ and tissue organizations and that every family's right to be informed about tissue donation is protected. Families may have many questions about tissue donation and there are many myths and misconceptions regarding tissue donation in the minds of the general public. Nurses can help answer these questions and dispel lingering inaccuracies about the donation process.

The Truth About Tissue Donation

From the grocery store tabloids to talk radio to popular TV programs and movies, Americans are subjected to a constant bombardment of misconception and fiction about tissue and organ donation and transplantation. These stories and shows can be very entertaining, but they also create confusion in the public mind and frustration for medical professionals.

Families must have the facts in order to make informed decisions about donation. Approximately 101,000 Americans wait for organ transplants and thousands more need life-enhancing tissue donation. It is also fact that America could meet the need for donated organs and tissues if more people supported donation. By separating fact from fiction, Americans will be better prepared to make the donation decisions for themselves and their loved ones.

Although the general public oftentimes perceives “organ” and “tissue” donation as synonymous, there is a distinct difference between the two opportunities for donation. There is also a difference in the pre donation status of the donor and the recovery of the organs and or organs/tissues.

The term “organ” pertains to the heart, kidneys, lungs, pancreas, liver and intestines. Organs that are to be recovered for the purpose of transplant into another human being must be recovered from an individual that is on a ventilator and continues to have a heart beat but has been declared brain dead and there is no chance of survival without ventilator support. The organs continue to be perfused with blood while the patient is on a ventilator. When it is time for the organs to be recovered, the aorta is clamped and blood flow stops. In certain circumstances organ donation may occur immediately after the cessation of heart beat when a patient is removed from a ventilator. This is known as donation after cardiac death. (DCD).

The term “tissue” refers to an “aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of a plant or an animal.” (Merriam-Webster’s online Collegiate Dictionary) Tissue can be skin, bone, corneas, bone marrow, heart valves and much more. Tissue can be recovered after cardiac death has been pronounced and up to 24 hours after death if certain criteria have been met.

History and Milestones of Tissue Donation

The history of tissue transplant dates back to the 1600’s when the first bone transplantation was recorded. In 1668 a Russian physician filled a defect in a soldier’s head using a piece of canine skull. This was considered to be an unchristian method and the physician was excommunicated. The graft had healed but was subsequently removed.

Other milestones in tissue transplant include:

- **1870** the first completely documented human tissue grafting was performed by a Swiss surgeon.
- **1905** Dr. Edward Zirm performed the first corneal transplant.
- **1908** the first skin allograft was performed by Dr Reverdin. That same year, Dr. Eric Lexer performed the first successful cadaver knee joint transplant.
- **1911** The French surgeon, Alexis Carrel, developed a method of joining blood vessels utilizing cadaveric vessels that made the transplantation of organs feasible.
- **1937** The first hospital-based blood bank in the United States was established at The Cook County Hospital in Chicago.
- **1949** The US Navy Tissue Bank was established
- **1955** The first fresh heart valve allograft was placed into the descending aorta.
- **1971** The first frozen heart valve was used as an allograft
- **1974** Cryopreserved human skin allograft is introduced
- **1976** The American Association of Tissue Banks was founded to facilitate the provision of transplantable tissue in quantities sufficient to meet national needs. It is the first peer organization dedicated to tissue banking.
- **1993** The Food and Drug Administration (FDA) published an interim final rule requiring the screening and testing of tissue donors for certain transmissible diseases such as HIV and hepatitis, as well as the screening of donors for behavioral risk factors.
- **1993 – Present.** The FDA continues its involvement in the regulation of all tissue banking processes including consent, screening, recovery, storage, processing, delivery and tracking of tissue for transplant. The FDA is concerned with public safety and has published rules to ensure tissue banks operate in a safe environment.

Types of tissue that can be donated and their uses

Allografts vs. Autografts

Autograft – second site donation from the patient.

Allograft – between members of the same species

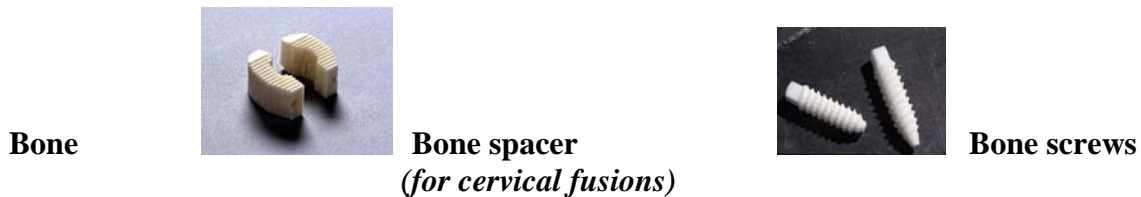
Autograft transplants involve taking tissue from one area of the body and using it on another part of the body. Autograft transplants always involve a second surgical site. This causes the patient additional discomfort, greater healing time and a greater chance of infection due to the multiple surgical sites. Autograft tissue is limited to a very small amount of tissue that can be recovered from the patient to be used elsewhere.

Allograft transplant involves tissue that is taken from a human donor for transplant into another human being. This is actually the safest and most effective form of tissue transplant that can occur. Without the need for a second surgical site, the patient has a shorter healing time, experiences less pain than with an autograft. Another advantage of

allograft tissue is that it can be shaped precisely to the desired specifications for a particular surgery.

The most common surgical procedures using donated tissues are:

- Spinal fusions
- Hip and knee replacements
- Anterior Cruciate Ligament (ACL) replacement
- Rotator cuff repair
- Orthopedic reconstruction due to cancer and trauma
- Surgical treatment for incontinence
- Heart valve replacement
- Ridge augmentation in dental procedures



The iliac crests and the long bones of the legs can be donated as well as the bones of the upper arms. The donated bones may be used to create special bone pieces such as screws in a range of sizes to accommodate the surgeons' needs for the transplant recipient.

Transplanted bone tissue can replace bone destroyed by tumors, trauma, and infection, healing limbs that might otherwise require amputation. Bone can also be used in spinal and oral surgeries, as well as procedures to correct birth defects and treat cancer patients.

Patients with debilitating pain due to compressed neck or back disks pressing on nerves, can benefit from an allograft implant, to fuse certain vertebrae, in order to take the pressure off the nerve. This surgery can mean the difference between a life-long disability and the chance at a normal life without pain.

Allograft bone tissue can also be used to repair defects such as scoliosis and Kyphosis in young adults. Having donated tissue available can reduce the time required under anesthesia for second site surgery to recover the patient's own tissue to use for the transplant. Healing time and recovery time can be shortened. Once the transplanted bone or soft tissue graft is accepted by the body, it is slowly converted into new living bone or soft tissue and incorporated into the body as a functional unit.

The rate at which allografts are used in surgical procedures has doubled in the United States during the past decade. An estimated one million bone grafts are performed each year in the United States.



Heart Valves

Heart valves can be donated for heart valve replacement. Heart valves direct the flow of blood in the heart and replacements are needed for defective valves especially in children. Half of donated valves are transplanted into children under the age of 15 and women of childbearing age. Children who receive a new heart valve to replace a leaky defective one can experience an increase in energy allowing them to participate in normal childhood activities.

Skin

Skin may be used to treat burn victims with life threatening injuries and has been used for this purpose since the second half of the 19th century. Over one million skin grafts are performed every year and another 500,000 patients could benefit from skin transplants if enough skin were available. Some burn victims are only able to survive because of the use of donated skin. Allograft skin use has been extended to conditions involving extensive skin loss such as ulcers, post-traumatic and post-surgical wounds, pressure ulcers and some autoimmune diseases.

Skin is generally recovered from the back, buttocks and back of the thighs. Skin donation is not visible and does not interfere with the option of having an open casket funeral service for the donor.

Veins

Veins are transplanted into patients with severe peripheral vascular disease to help avoid the need for amputation.

Femoral veins replace defective vessels for patients suffering from chronic venous insufficiency.

Saphenous veins are used in heart bypass surgeries.



Cartilage and tendons

Connective tissue is used to replace injured tissue around the knee, to correct abnormalities of the eyelid and reshape facial disfigurement. This type of tissue can be used to repair anterior cruciate ligament (ACL) tears. The ACL can be replaced

arthroscopically with donated ligament and screws that have been pre-shaped from donated tissue.

Corneas/Eyes

Corneas can be transplanted to restore vision to others with corneal defects, injuries or diseases which have caused blindness. The sclera, or white part of the eye, is a tough fibrous tissue that can be used for patch grafts for eye surgeries or for dental procedures.



Specially trained technicians are responsible for the tissue removal and take great care to restore the donor to his/her normal appearance through the use of prosthetic devices when necessary. This will allow the family the option of having an open casket funeral service if they wish.

Frequently Asked Question and Myths & Misconceptions

Frequently asked questions about tissue donation

Who can donate tissues?

Almost anyone of any age can be a tissue donor. The tissue that can be donated will vary depending on the medical condition of the patient at the time of death. This will be discussed with the family at the time of consent. The tissue bank will determine what tissue a donor can give based on the past and current medical history, medications taken, Lab results, chest x-rays and other criteria. If the patient is not suitable for donation for transplant, they may qualify for donation for research. If you want to be a donor, do not rule yourself out, regardless of any diseases or disabilities you might have. Criteria on donation is ever-changing so let the professionals at your local tissue bank decide on suitability at the time of death.

Does my religion accept donation?

Most religions support and consider donation an act of charity. It is a way to affirm the deceased's generosity and goodness. The following religious views are not inclusive of all religions. For more information, individuals are encouraged to speak to the leadership of their specific faith.



Religious views

Amish - The Amish consent to transplantation if they know it is for the health and welfare of the transplant recipient.

Baptist – Organ and tissue transplants are generally approved when they offer real medical hope for the recipients.

Buddhism – Buddhists believe organ and tissue donation is a matter that should be left to an individual's conscience. There is no written resolution on the issue.

Catholicism – Catholics view organ and tissue donation as an act of charity fraternal love and self sacrifice. Transplants are ethically and morally acceptable to the Vatican.

Christian Church (Disciples of Christ) – There are no prohibitions against organ and tissue transplantation.

Church of Christ Scientist – Christian Scientists do not take a specific position on transplants or organ and tissue donation. Christian Scientists normally rely on spiritual, rather than medical means for healing. The question of organ and tissue donation is left to the individual church member.

Episcopal – In 1982 the Episcopal Church passed a resolution recognizing the life-giving benefits of organ, blood and tissue donation and encouraging all Christians to become organ, blood and tissue donors.

Greek Orthodox – Transplants, such as skin-grafting and blood transfusions from one human to another, always have been acceptable. This is extended to include organ and tissue transplants.

Gypsies – Gypsies on the whole, are against organ and tissue donation. Although they have no formal resolution, their opposition is associated with their belief about the after-life. Gypsies believe that for one year after a person dies, the soul retraces its steps. All of the body parts must be intact because the soul maintains a physical shape.

Hinduism – Hindus are not prohibited by religious law from donating their organs and tissues, according to the Hindu Temple Society of North America. This act is an individual decision.

Islam – The Moslem Religious Council initially rejected organ and tissue donation by followers of Islam in 1983; but it has reversed its position, provided that donors consent in writing in advance.

Jehovah's Witnesses – According to the Watch Tower Society, the legal corporation for the religion, Jehovah's Witnesses do not encourage organ and tissue donation, but believe it is a matter best left to an individual's conscience. All organs and tissues, however, must be completely drained of blood before transplantation.

Judaism Orthodox (Traditional) – The sanctity of the human body covers each of its members and organs. So where any part of the body is separated from the body, it too, requires burial. However, when an organ or tissue is to be transplanted to save the life of a patient or improve his health, then it is permitted.

Lutheran – The ability to transplant organs and tissues from a deceased to a living person is considered a genuine medical advance.

Mormons – The Church of Jesus Christ of Latter-day Saints considers the decision to donate organs and tissues a personal one. Jerry Cahill, director of Public Affairs for the Mormon Church says, "Mormons must individually weigh the advantages and disadvantages of transplantation and choose the one that will bring them peace and comfort. The Church does not interpose any objection to an individual decision in favor of organ and tissue donation."

Presbyterian – Presbyterians encourage and endorse organ and tissue donation. They respect individual conscience and a person's right to make decisions regarding his own body.

Protestantism – Protestants encourage and endorse organ and tissue donation. The Protestant faith respects an individual's conscience and a person's right to make decisions regarding his or her own body.

Seventh Day Adventist – The individual and the family have the right to receive or to donate those organs and tissues that will restore any of the senses or will prolong the life profitably.

Will it cost anything to donate and will the family be rewarded for the donation?

There is no cost to donation. If the body is going to be embalmed after donation and the funeral home charges a fee for this, the tissue bank will cover that cost or reimburse the

family if they are charged. Donation is considered an act of charity and the family is not rewarded for the gift. Also, federal law makes it illegal to sell human organs and tissues.

Will the donation affect funeral arrangements?

No. Donation does not interfere with funeral or burial arrangements. Also, the donation will not jeopardize an open-casket service.

Can some tissues be donated and others declined?

Yes. The donor may make pre arrangements to donate certain tissues and not others. The family may also consent to donation of some tissue and not others. Each body system is covered and explained to the family so that they will have a good understanding of what tissue are available to donate and what tissues they would like to donate.

Myths and Misconceptions

MYTH: Doctors will not try to save my life if they know I want to be a donor.

FACT: The medical staff trying to save lives is completely separate from the transplant team. The doctors who treat a patient at the time of death are in no way involved with transplant programs or potential recipients. Donor organizations serve as the intermediaries between attending physicians and hospitals where a donation occurs and the transplant programs and transplant teams. Hospitals will notify donor organizations when a potential donor is identified, and donation is considered only after every effort has been made to save the patient's life.

MYTH: People can recover from brain death.

FACT: People can recover from comas, but not brain death. Coma and brain death are not the same. Brain death is final.

MYTH: The rich and famous on the U.S. waiting list for organs get preferential treatment.

FACT: The computerized matching system does not select recipients based on fame or wealth. Organs are matched by blood and tissue typing, organ size, medical urgency, waiting time, and geographic location.

MYTH: Donation will disfigure my body.

FACT: Organs and tissues are removed in procedures similar to surgery and all incisions are closed at the conclusion of the surgery. An open casket funeral is possible after donation.

MYTH: Doctors might take organs before the patient is really dead.

FACT: Most fears about donation come from misunderstanding of brain death. Organs can be donated only after brain death is diagnosed and declared in a hospital. After brain death occurs, the body can be maintained for a short time by mechanical support systems before the organs begin to deteriorate. This is not "life support." When on mechanical support, the body has color and is warm to the touch, but it is not alive. If brain death is not clearly and completely explained, family members may be confused. But the fact is that brain death is not a coma. Brain death is irreversible. Brain death is death.

Tissue and cornea donation is possible after brain death or cardio-respiratory (heart-lung) death. This means that there are more opportunities for people to become tissue and cornea donors because mechanical support is not required to maintain tissues for transplant.

Current Florida Legislation, Conditions of Participation for Hospitals

Florida Legislation

The Uniform Anatomical Gift Act was first established in 1968 to overcome the donor shortage. It stated that an individual, upon death, could donate their organs for medical purposes by signing a document before witnesses. This was the first milestone in attempting to overcome the donor shortage. The second milestone came in May of 2003 when the Governor of Florida signed into law the Nick Oelrich Gift of Life Act. This new legislation amended the Florida Anatomical Gift Act by making a donor's anatomical gift irrevocable by the next of kin unless there are two witnesses to the revocation, one of which cannot be a family member. This bill was enacted in order to prevent family members from overturning the decision of the deceased to be a donor. It specifically states: "A family member, guardian, representative ad litem, or health care surrogate, of an adult donor who has made an anatomical gift pursuant to subsection (2) may not modify, prevent or deny a donor's wish or intent to make an anatomical gift from being made after the donor's death." First-person consent is a law that will allow a person to legally register a binding decision to become an organ and tissue donor upon their death. Additional witnesses or additional consent from the family will not be required to carry out the wishes of the donor. Currently 42 states have, in legislation or "on the books," a form of first-person consent.

Even though agencies have the backing of the Uniform Anatomical Gift Act, only a few donor agencies truly use the first-person consent. Most recovery agencies use the donor registry as a basis for working with donor families as opposed to proceeding with donation without the family's or legal next of kin consent. The recovery agencies that do not use the first-person consent in its entirety say they would not proceed with donation if

the family objected due to the potential of negative press that would hurt donation as a whole.

Hospital Conditions of Participation and JCAHO Standards

JCAHO Standards reflect the requirements set forth at the federal level by the Centers for Medicare and Medicaid Conditions of Participation for hospitals



The hospital must have and implement written protocols that:

- (1) Incorporate an agreement with an Organ Procurement Organization (OPO), under which it must notify, in a timely manner, individuals whose death is imminent or who have died in the hospital. Every death, or imminent death, must be reported to the OPO regardless of the cause of death or surrounding circumstances. The OPO determines medical suitability for organ donation.
- (2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of all usable tissue and eyes.
- (3) Ensure, in collaboration with the designated OPO and tissue bank, that the family of each potential donor is informed of its options to donate organs, tissue, or eyes or to decline to donate.
- (4) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors.
- (5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in: educating staff on donation issues; reviewing death records to improve identification of potential donors; and maintaining the potential donor while necessary testing and placement of potential donated organs, tissues and eyes take place.

JCAHO LD.3.110 A.4 Hospitals must have specific SOP's that compel early referral of potential donors to the OPO

JCAHO LD.3.110 A.11 Hospitals must keep referral records

JCAHO LD.3.110 A.4 Hospitals must create critical pathways (clinical triggers) that are specific to tissue donation.

JCAHO LD.3.110 A.12 Hospitals must, in conjunction with the OPO and tissue bank, conduct monthly to quarterly death record audits

JCAHO LD.3.110 A 12 Hospitals must educate staff about donation issues

Safety of Tissue Transplants

There are risks and benefits with any medical procedure, and tissue transplants are no different. There is a risk of infection from surface contamination and viral or spore transfer with tissue transplants. The most common type of allograft infection is bacterial, which is caused from contamination of the graft or the wound. Viral infection, hepatitis B and C, and HIV-1 and HIV-2 infection are also cause for concern. The risk of hepatitis B after blood transfusion is 1/63,000. The risk of hepatitis C is 1/100,000 and the risk of HIV is 1/1,000,000. The risk of HIV after bone transplantation is 1/1,500,000. In contrast, the risk of death due to pregnancy is 1/10,000, the risk of death from administration of penicillin is 1/30,000 and the risk of death with oral contraceptives is 1/50,000. There are no reported cases of transmission of a malignancy (cancer) due to tissue transplantation.

There are steps being taken to reduce or eliminate the transmission of communicable diseases with tissue transplants.

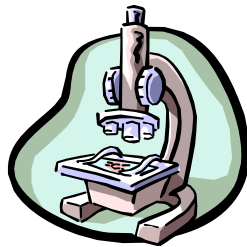
The FDA

The FDA is concerned with public safety and has established rules and regulations to ensure tissue banks operate in a safe environment. Tissue banks are required to register with the FDA and must have specific donor screening requirements. After the consent is obtained a history from the donor's primary caregiver must be obtained which should include a listing of any prior infection and risk factors such as male homosexuality, sex for money, illegal drug use or hemophilia. A physical examination must be performed to assess the donor for needle wounds or evidence of infection. Screening tests are performed on tissue and blood for infectious diseases. Tissues are tested for the presence of viral or bacterial diseases including HIV, Hepatitis B and C, syphilis and other infectious diseases. Tests must be run by a lab that is CLIA certified and registered with the FDA. Tests must also be approved by the FDA for cadaveric donors.

Tissue banks are expected to have a system in place that documents every step of the process from screening to recovery, to the final distribution that ensures tissue is free of disease. The FDA conducts periodic inspections of tissue banks to ensure compliance with published rules. The Current Good Tissue Practices" (CGTP) which went into effect in May 2005 requires all tissue banks to establish a quality program designed to reduce the risk of introduction, transmission or spread of communicable disease through tissue transplantation.

The AATB

The American Association of Tissue Banks (AATB) is dedicated to ensuring that human tissues intended for transplantation are safe and free of infectious disease, of uniform high quality and available in quantities sufficient to meet national needs. Since 1984 the AATB has published the only authoritative industry standards for tissue banks – the AATB’s Standards for Tissue Banking. It is the first peer organization dedicated to tissue banking. The AATB also inspects participant tissue banks and will award Accreditation for those banks that meet the Standards set forth by the Association. Tissue bank personnel may also achieve Certification through the Association and receive the status of Certified Tissue Bank Specialist. (CTBS)



Donation for Research and Education

Donors who do not meet current transplant criteria may be able to donate tissues for research and education. There are many research foundations and universities across the country that are able to use donated tissue to study diseases such as Alzheimer’s and Parkinson’s as well as traumatic brain injuries. The need for tissues for medical research and education is urgent and plays an important role in improving lives. The goal of medical scientists, physicians and surgeons throughout the world is to improve the health, fitness and quality of life of the general public. Researchers work diligently to find solutions to the health problems that plague our society. For every new drug or medical device that reaches the shelves of the local pharmacy or the hands of a physician, there are countless hours of research that allow for the successful testing and validation of the respective product.

All the current and future surgical procedures and techniques available to us are dependent on effective, proven research. Medical professionals and research institutions worldwide commit their time, knowledge and resources to studying the causes and effects of various diseases in order to provide better healthcare and longevity of life. This commitment of time and substance allows researchers the opportunity to affect life-saving changes through advances in medical science and knowledge.

Research may include the identification of risk factors for various diseases to develop better methods of disease diagnosis, treatment and prevention. As doctors and scientists work toward solutions for today’s medical problems it is most always necessary to study

the effects of treatment on human tissues and to categorize the characteristics and symptoms of diseased tissue. Donated tissues can help develop new methods and education in tissue transplantation that will allow for better surgical procedures, reduced pain and shortened recovery times. In addition, tissue donation helps in saving and enhancing lives. Tissue dedicated to research is an integral part of the continued movement toward improving life and health through medicine.

For more information about organ and tissue donation, visit the Donate Life Florida website at www.fcod.org or www.donorcare.org Southeast Tissue Alliance
www.lifequestfla.org Lifequest Organ Procurement Organization

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Post Test for the Truth About Tissue Donation

- 1) The first frozen heart valve was used as an allograft in the _____ .
 - a) 1950's
 - b) 1960's
 - c) 1970's

- 2) According to CMS Hospital Conditions of Participation for Organ Donation, hospitals do not need to report every death or imminent death to an Organ Procurement Organization.
 - a) True
 - b) False

- 3) First person consent for tissue donation is legal in the State of Florida
 - a) True
 - b) False

- 4) Healing time can be shortened for patients when _____ tissue is used.
 - a) Allograft
 - b) Autograft

- 5) People over the age of 85 can still be donors.
 - a) True
 - b) False

- 6) Tissue donation will prevent the family from having an open casket
 - a) True
 - b) False

- 7) Most religions support and consider donation an act of charity.
 - a) True
 - b) False

- 8) The sclera cannot be used for surgery because it is not sterile.
 - a) True
 - b) False

- 9) The FDA regulates tissue banks, and sets forth certain "rules" that must be followed by tissue banks.
 - a) True
 - b) False

- 10) People can recover from brain death
 - a) True
 - b) False

Name: (please print) _____

License Number _____ Profession (circle one) ARNP CNS RN LPN

E-mail address: _____

Employer: _____

Date of Completion of course: _____