

EAST CAROLINA UNIVERSITY

INFECTION CONTROL PLAN

Safe Medical Devices
Needlestick Safety & Prevention Act Addendum

Date Originated: October 1, 2002
Date Approved: November 2002

Dates Reviewed: 11/02, 07/04,
10/7/08, 6/5/12, 6/7/16, 6/5/18,
12/3/19

Page 1 of 12

Approved by:

Mark Stacy, MD
Vice-Chancellor Health Sciences

Paul Barry, MD
Director, Prospective Health

Paul Cook, MD
Chairman, Infection Control Committee
Committee

Daniel Martin, PhD
Chairman, Biological Safety

Authority: The Needlestick Safety and Prevention Act (H.R. 5178) mandated that the 1991 OSHA/Bloodborne Pathogen Standard (29CFR 1910.1030) be revised to strengthen the requirements related to the use of safety-engineered sharp devices, effective April 18, 2001. This document is added to the ECU Bloodborne Pathogen Exposure Control Plan which is reviewed and updated annually, and made available to employees, to comply with this legislation.

- I. Addendum to ECU Bloodborne Pathogen Exposure Control Plan
 - Purpose:
 - A. Document that safer medical devices designed to eliminate or minimize occupational exposure have been evaluated and implemented
 - B. Review and update annually this policy and report on the outcomes
 - 1. Including documentation of input from non-managerial employee
 - 2. Reflecting changes in technology

- II. Sharps Injury Log
 - A. Maintained by Office Prospective Health
 - B. Includes information on
 - 1. Type and brand of device involved in exposure incident
 - 2. Department or work area
 - 3. How exposure occurred
 - C. Ensures confidentiality when recording and maintaining information in the sharps injury log.
 - 1. Exposure evaluations are conducted using a code number, not by name
 - 2. Exposures reported on the OSHA log by Office of Environmental Health and Safety will be posted using a code and not by name
 - D. Results will be presented to ECU Infection Control Committee and Brody School of Medicine Product Standardization Committee annually.

- III. Sharps Safety Devices
 - A. In order to prevent needle sticks injuries, the following principles should be followed:
 - 1. Eliminate unnecessary needles and sharps whenever possible
 - 2. Give priority to implementing safety blood drawing and vascular access devices
 - 3. More specific guidelines are provided below for specific applications
 - B. Blood Drawing
 - 1. Implement blood drawing devices with integrated safety features
 - 2. Replace needles with needleless or blunt cannula devices with IV lines
 - 3. Use automatically retracting finger/heel stick lancets
 - 4. Switch from glass to plastic capillary tubes or Mylar coated glass or alternative methods for measuring hemoglobin
 - 5. Replace glass blood collection vacuum tubes with plastic tubes
 - 6. Do not manually recap or remove needles from blood-drawing devices
 - 7. Do not reuse blood tube holders which require manipulation of a blood-filled needle
 - 8. Do not inject blood through a stopper into a vacuum tube using an exposed needle
 - C. Vascular access – implement safety vascular access catheters that shield or

blunt the stylus before or during withdrawal from the patient

D. Infusion – convert to needleless or recessed needle IV infusion systems

E. Injection

1. For syringes used for subcutaneous or intramuscular injections, convert to devices with integrated safety features such as sliding sleeves, retractable needles, and hinged caps, etc
2. Do not use syringes for venous blood drawing due to increased needle sticks rash
3. Use safety-designed prefilled syringes where available

F. Surgery

1. Use staples, adhesive strips, or tissue adhesive when possible; to reduce the use of sharp-tip suture needles
2. Use scalpel blades with safety features such as round-tipped scalpel blades, retracting blades, or shielded blade scalpels
3. Avoid manual retraction by using mechanical retraction devices
4. Use alternative cutting methods rather than scalpels when possible
5. Eliminate equipment that is unnecessarily sharp

IV. Responsibility

A. At Brody School of Medicine, the Product Standardization Committee is responsible for recommending equipment, supplies, and medical devices to be purchased by the Medical Store room and used in the Brody Clinics. The Safe Needle/Device sub committee of the Product Standardization Committee is charged to develop a process for evaluation of such devices and to make recommendations about products to be purchased based upon these evaluations

1. The Safe Needle/Devices subcommittee is comprised of the Infection Control nurse, head nurses and staff nurses from each clinic, a medical technologist from Pathology, a representative from research, the medical school and the dental school.
2. The products selected for evaluation will be used and rated by front-line clinic personnel. Use of the devices will be demonstrated to the Safe Needle Device subcommittee by the sales representative. Each subcommittee representative will train the department/clinic in appropriate use of the device. They will document in writing the date of the training, name of the device and name of trainees. This training record (App F) will be returned together with the appropriate ratings form (see appendix A-E) by the departmental representative after the frontline users have had ample time to handle and use the device. The individual ratings will be tabulated and summarized.
3. Results will be presented to the Product Standardization Committee with recommendations regarding purchase and implementation
4. Results of the evaluations will be summarized annually in a report which will become an addendum to the ECU Bloodborne Pathogen Exposure Control Plan
5. The efficacy of implemented devices in reducing exposure events will be tracked using exposure data summarized annually by the Office of Prospective Health and presented to the Infection Control Committee and to the Safe Needle/Devices subcommittee

6. Implemented devices will be re-evaluated on a continuing basis as new technologies are developed
7. Devices used in research activities shall include evaluations by research user

- B. The ECU Student Health Service will conduct a separate evaluation process for the devices they use, following similar principles.
1. Front line clinical personnel will evaluate the devices.
 2. Student Health Service will directly purchase the chosen devices.
 3. An annual report documenting the process for the prior 12 months will be submitted to Infection Control, annually.

V. Exemptions

OSHA requires that employers substitute safety needle/sharps systems for all non-safety systems. Exceptions are allowed if:

1. The safety of the patient would be adversely affected
2. The success of the procedure would be adversely affected

In order to obtain an exemption from using a specific safety device for a specific use, the Exception Form (App G) is completed and submitted to the BSOM Product Standardization Committee's Safe Needle/Devices Task Force, Infection Control Nurse, or Student Health Service equivalent. This form documents the reasons for non-use.

Appendix A

ECU SAFE MEDICAL DEVICE EVALUATION FORM
SHARPS DISPOSAL CONTAINERS

Brand _____

Name/Title _____

Department _____

Date _____

- disagree agree
1. The container's shape, markings, or color, imply danger which
Can be understood by visitors, children and patients.....1 2 3 4 5 N/A
 2. The implied warning of danger can be seen from the angle at which
people commonly view it; very short people, people in wheel
chairs, children, etc.).....1 2 3 4 5 N/A
 3. The container can be placed in a location that is easily accessible during
emergency procedures.....1 2 3 4 5 N/A
 4. The container's purpose is self-explanatory and easily understood
by a worker who may be pressed for time or unfamiliar with the
clinical setting1 2 3 4 5 N/A
 5. The container can accept sharps from any direction desired1 2 3 4 5 N/A
 6. The container can accept all sizes and shapes of sharps1 2 3 4 5 N/A
 7. The container allows single handed operation. (Only the hand holding
the sharp should be near the container opening).....1 2 3 4 5 N/A
 8. It is difficult to reach in and remove a sharp.....1 2 3 4 5 N/A
 9. Sharps can go into the container without getting caught on the
opening or any molded shapes in the interior1 2 3 4 5 N/A
 10. The container can be placed within arm's reach.....1 2 3 4 5 N/A
 11. The container is puncture resistant.....1 2 3 4 5 N/A
 12. No sharp edges in construction or materials1 2 3 4 5 N/A
 13. The user can determine easily, from various viewing angles, when
the container is at the full line.....1 2 3 4 5 N/A
 14. When the container is to be used free-standing, (no mounting
bracket), it is stable and unlikely to tip over1 2 3 4 5 N/A
 15. Mounting system durable, safe, secure, cleanable and lockable.....1 2 3 4 5 N/A
 16. The container is large enough to accept all sizes and shapes of
sharps, including 50 ml preloaded syringes1 2 3 4 5 N/A
 17. It is safe to close the container. (Sharps should not protrude
into the path of hands attempting to close the container)1 2 3 4 5 N/A
 18. The container closes securely under all circumstances.....1 2 3 4 5 N/A
 19. The product has handles which allow you to safely transport a
full container1 2 3 4 5 N/A
 20. The product **does not** require extensive training to operate correctly1 2 3 4 5 N/A

Appendix B

**ECU SAFE MEDICAL DEVICE EVALUATION FORM
PHLEBOTOMY DEVICE/IV ACCESS DEVICE**

Choose on by √

Finger stick device _____ Heal stick device _____
Butterfly (winged steel needle) _____ Vacutainer _____
Vein access needle _____

Brand _____

Name/Title _____

Department _____

Date _____

HEALTHCARE WORKERS SAFETY

disagree agree

1. The device prevents needle sticks during use during use1 2 3 4 5
2. The device prevents needle sticks after use1 2 3 4 5
3. The safety feature can be activated using one-handed techniques.....1 2 3 4 5
4. The safety feature does not interfere with blood draw.....1 2 3 4 5
5. The device provides a visible blood flashback1 2 3 4 5
6. The device creates extra risk of sprays, blood leakage, and/or drips1 2 3 4 5
7. The device is easy to handle wearing gloves1 2 3 4 5
8. The safety feature is reliable when activated properly.....1 2 3 4 5
9. The safety device has an unmistakable indicator that it has been
activated1 2 3 4 5

PATIENT SAFETY AND COMFORT

1. The device can be used/adapted for adults and children1 2 3 4 5
2. The device does not cause ↑ discomfort to patients.....1 2 3 4 5
3. The device can be used for various sizes of patients1 2 3 4 5

EASE OF USE AND TRAINING

1. The device can be used properly without extensive training1 2 3 4 5
2. The device can be used by staff with a variety of hand sizes.....1 2 3 4 5
3. The safety feature requires more time to use than a non-safety device.....1 2 3 4 5
4. The safety feature interferes with normal use of this product.....1 2 3 4 5
5. It is easy to identify type and size of product from the packaging1 2 3 4 5

COMPATIBILITY

1. The device is compatible with products from variety of suppliers1 2 3 4 5
2. The device is easy to dispose of in available sharps containers.....1 2 3 4 5
3. The device significantly increases volume of waste in sharps containers1 2 3 4 5

OVERALL

Would you recommend this device.....yes no

If no, please √ reason:

Hard to disengage _____ Change of technique _____ Difficult to use _____
Too many steps _____ Requires more training _____ Other _____

Appendix C

**ECU SAFE MEDICAL DEVICE EVALUATION FORM
SURGICAL SHARPS**

Brand _____

Name/Title _____

Department _____

Date _____

HEALTHCARE WORKERS SAFETY

disagree agree

- 1. The device minimizes the risk of sharp sticks during use.....1 2 3 4 5
- 2. The device minimizes the risk of sharp sticks after use.....1 2 3 4 5
- 3. The safety feature can be activated using one-handed techniques1 2 3 4 5
- 4. The device creates extra risk of sprays, blood leakage, and/or drips .1 2 3 4 5
- 5. The device is easy to handle wearing gloves1 2 3 4 5
- 6. The safety device has an unmistakable indicator that the feature has been activated.....1 2 3 4 5
- 7. The safety feature is reliable when activated properly.....1 2 3 4 5
- 8. The exposed sharp is permanently blunted or covered after use and prior to disposal.....1 2 3 4 5

PATIENT SAFETY AND COMFORT

- 1. The device can be used/adapted for adults and children.....1 2 3 4 5
- 2. The device does not cause ↑ discomfort to patients.....1 2 3 4 5
- 3. The device can be used for various sizes of patients1 2 3 4 5

EASE OF USE AND TRAINING

- 1. The device can be used properly without extensive training1 2 3 4 5
- 2. The device can be used by staff with a variety of hand sizes.....1 2 3 4 5
- 3. The safety feature requires more time to use than a non-safety device1 2 3 4 5
- 4. The safety feature interferes with normal use of this product.....1 2 3 4 5
- 5. It is easy to identify type and size of product from the packaging.....1 2 3 4 5

OVERALL

Would you recommend this device.....yes no

If no, please √ reason:

- Hard to disengage _____ Change of technique _____ Difficult to use _____
- Too many steps _____ Requires more training _____ Other _____

Appendix D

ECU SAFE MEDICAL DEVICE EVALUATION FORM
SAFETY NEEDLE/SYRINGE DEVICE

Brand _____

Name/Title _____

Department _____

Date _____

HEALTHCARE WORKER SAFETY

disagree agree

- 1. The syringe functions satisfactorily for its intended purpose 1 2 3 4 5
- 2. The safety feature does not interfere with normal use of this product 1 2 3 4 5
- 3. The device prevents needle sticks during use..... 1 2 3 4 5
- 4. The device prevents needle sticks after use 1 2 3 4 5
- 5. The safety feature can be activated using the one-handed techniques 1 2 3 4 5
- 6. This device has an unmistakable indicator that the safety feature is activated 1 2 3 4 5
- 7. The device does not create any extra risk of sprays, blood leakage and/or drips 1 2 3 4 5
- 8. The device is easy to handle wearing gloves 1 2 3 4 5
- 9. The safety feature is reliable when activated properly..... 1 2 3 4 5

PATIENT SAFETY AND COMFORT

- 1. The device can be used/adapted for adults and children 1 2 3 4 5
- 2. The device does not cause ↑ discomfort to patient 1 2 3 4 5
- 3. The device can be used for various sizes of patients 1 2 3 4 5
- 4. The dosage visibility in the syringe is not a problem..... 1 2 3 4 5

EASE OF USE AND TRAINING

- 1. The device can be used properly without extensive training 1 2 3 4 5
- 2. The device can be used by staff with a variety of hand sizes..... 1 2 3 4 5
- 3. The safety feature does not require more time to use than a non-safety device..... 1 2 3 4 5
- 4. The safety feature does not interfere with normal use of this product 1 2 3 4 5
- 5. It is easy to identify type and size of product from the packaging 1 2 3 4 5

COMPATIBILITY

- 1. The device is compatible with products from variety of suppliers 1 2 3 4 5
- 2. The device is easy to dispose of in available sharps containers..... 1 2 3 4 5
- 3. Device is compatible with other devices it may have to connect to (blunt cannulae/luer connectors) 1 2 3 4 5

OVERALL

Would you recommend this device..... yes no

If no, please √ reason:

Hare to disengage _____

Change of technique _____

Difficult to use _____

Too many steps _____

Requires more training _____

Other _____

**ECU SAFE MEDICAL DEVICE EVALUATION FORM
IV CONNECTORS**

Brand _____

Name/Title _____

Department _____

Date _____

HEALTHCARE WORKER SAFETY

Disagree agree

- 1. The device prevents needle sticks during use..... 1 2 3 4 5
- 2. The device prevents needle sticks after use 1 2 3 4 5
- 3. The device attaches securely to catheter port 1 2 3 4 5
- 4. The device attaches or locks a Y-site (e.g. piggybacking)..... 1 2 3 4 5
- 5. The device does not create extra risk of sprays, blood leakage, and/or drips 1 2 3 4 5
- 6. The device is easy to handle wearing gloves 1 2 3 4 5
- 7. The safety feature is reliable when activated properly..... 1 2 3 4 5

PATIENT SAFETY AND COMFORT

- 1. The device can be used/adapted for adults and children 1 2 3 4 5
- 2. The device does not cause ↑ discomfort to patient 1 2 3 4 5
- 3. The device can be used for various sizes of patients 1 2 3 4 5

EASE OF USE AND TRAINING

- 1. The device can be used properly without extensive training 1 2 3 4 5
- 2. The device can be used by staff with a variety of hand sizes..... 1 2 3 4 5
- 3. The safety feature does not require more time to use than a non-safety device 1 2 3 4 5
- 4. The safety feature does not interfere with normal use of this product..... 1 2 3 4 5
- 5. It is easy to identify type and size of product from the packaging 1 2 3 4 5

COMATIBILITY

- 1. The device is compatible with products from variety of suppliers 1 2 3 4 5
- 2. The device is easy to dispose of in available sharps containers..... 1 2 3 4 5
- 3. The device does not significantly increase volume of waste in sharps containers 1 2 3 4 5

OVERALL

Would you recommend this device..... yes no

If no, please √ reason:

Hard to disengage _____

Change of technique _____

Difficult to use _____

Too many steps _____

Requires more training _____

Other _____

Appendix F

Instructions for Exception form:

The Occupational Safety and Health Administration requires that wherever possible, employers must substitute safety needle/sharps systems for non-safety systems.

Exceptions are allowed for the following:

1. If safety of patient would be affected
2. If success of the procedure would be affected.

Fill out all parts of the Exception form.

- . List the specific non-safety needle/needles that are needed.
- . List the specific procedure/procedures the safety needle will not work for.
- . List the safety devices that have been tried for this procedure, or list “no safety device currently available.”
- . Give the specific reason the safety device is not appropriate for these procedures.
- . List the specific safety procedures that will be used to prevent exposure to the non-safety needle systems.
- . Print the name of the person submitting the request so they can be contacted if further information is needed.

Forward to your Nurse Leadership representative or to Product Standardization Committee Safe Needle/Devices Task Force.

ECU Safety Sharps Exception Documentation

Date _____ Department _____ Center _____

Non-Safety Needle needed _____

Procedure that safety needle will not work for:

Specific devices evaluated for use on this procedure:

(please list brand or type, i.e. B/Braun, J&J, flip cap, retractable, etc.)

Specific reason safety needle is not appropriate:

Providers that do this procedure

Safety procedures that will be used to prevent exposure to non-safety needle:

Submitted by (please print) _____

Approved by _____

Date: _____

ECU Infection Control Nurse or designee

Return to Product Standardization Committee Safety Needle/Devices Subcommittee

Safe Medical Device Task Force

The task force did not meet in 2018. The team usually meets twice a year or sooner if necessary. It has been one year since the evaluations of safety sharp products now in use at ECU. Front line users, in the departments where they are most frequently used, were surveyed as to their preferences in devices and if they had suggestions of new products to try that they had seen used or had spoken to a representative about. There was one request for a safety spinal needle to be used during an amniocentesis. This request is being addressed at this time by contacting safety needle representatives and ECU Purchasing Department.

ECU has not experienced problems with the current safety products but will continue to try out and evaluate new products as they become available. Currently, products utilized are safe, easy to use and operate, and are the preferred brands by clinical staff. As supplies are ordered in the future, other brands may be considered and evaluated by staff.

Safety Device Committee

Cardiovascular Center Donna Lou Edwards ResearchDr. Aloor
Dermatology Lisa Jones Medical SchoolRuss Price
ECU Womens Jennifer Rook Pathology med techDavid Van Cura
Endocrinology..... Cathy Rademacher
FiretowerNancy Ahmed
FPC Jennifer Blizzard *Chair Sharon Shipley, RN
Human PerformanceChuck Tanner
ID ClinicChaundra Wiggins
Internal MedicineShanita Bennett
MRIDoes not use any sharps
NephrologyKelli Cox
Neurology Lovie Powers
OB/GYN Modules B,C,J.....Jennifer Rook
Peds/Adult Erica Turner
Peds Hem/OncRhonda Strickland
Peds Outpatient Sandy Goff
Peds SpecialtyRhonda Strickland
PMRKim Webster
Physical TherapyAlex Durland
Plastic SurgeryHeather Gauqie
Prospective HealthLori Willford
PulmonaryLaura Hignite
Rheumatology Brandi Mills
Ross Hall (Dental)Misti Taylor
SurgeryDonna Fredette
Tedi Bearno sharps
Ward Sports MedicineMike Hanley