

AGH ASRI	ALLEGHENY GENERAL HOSPITAL ALLEGHENY-SINGER RESEARCH INSTITUTE	Protocol for the Procurement and Use of Anatomic Materials Electronic Form – INTERNAL LABS BIOSKILLS, RESEARCH PROJECTS ONLY
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****COMPLETE THIS FORM IN ITS ENTIRETY. INCOMPLETE FORMS WILL NOT BE ACCEPTED.****
 Protocols for the Procurement and Use of Anatomic Materials are approved for a one year time period.

Title of the Protocol: Safe dissection parameters of the anconeus rotational flap for soft tissue coverage at the elbow

Principal Investigator(s): Mark Carl Miller, PhD

Department: Biomechanics Lab, Ortho Surgery

Cost Center: 19104309

Phone #: 412-359-5282

Pager#: _____

Fax #: _____

e-mail: mark.c.miller@ahn.org

Funding Source: choose one (specify who is responsible for expenses associated with the procurement, storage and disposal of the anatomic material requested for use in this protocol)

Internal (specify)

External (specify)

This protocol is a: New Protocol

Revision to a current protocol – (Provide Protocol Number) _____

Renewal – (Provide Protocol Number) _____

This protocol is for the purpose of (choose one): Research Education

Specimen and Procurement Detail:

	# of Specimens	Whole Cadaver	Partial: Identify Specific Body Part
Embalmed		<input type="checkbox"/>	<input type="checkbox"/> -
Fresh		<input type="checkbox"/>	<input type="checkbox"/> -
Frozen	9	<input type="checkbox"/>	<input checked="" type="checkbox"/> - arm from mid humerus to fingertips

Vendor information: (choose one)

I prefer to purchase my specimens from:

Telephone # _____

Contact name _____

I have no preference

Specimens to be provided by an external sponsor: Specify sponsor _____

Required arrival date of specimens:

Note: Specimens should be requested a minimum of 8 weeks prior to need.

Specimens will be transferred from protocol# _____ to this protocol

I/we guarantee that all anatomic materials in my/our utilization protocol will follow the guidelines provided in the AGH/ASRI Policy and Procedure entitled "Procurement of Anatomic Materials for Education and Research", the Uniform Anatomical Gift Act (2006), and the Human Gifts Registry.

Signature: Mark Miller
Principal Investigator

Date: 17 June 20

Signature: _____
Co-Investigator

Date: _____

FOR OFFICE USE ONLY:

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ALLEGHENY-SINGER RESEARCH INSTITUTE**

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Approval
Signature:

Edward P. Lynch MD
Department of Laboratory Medicine

Date: *06/24/2020*

1. **State the scientific or educational objectives of the protocol.** Describe the potential value of the protocol with respect to human health, advancement of knowledge or good of society.

There are no established parameters to use in safely dissecting out the anconeus muscle for use as a rotational flap for soft tissue coverage at the elbow. While with free flaps it is necessary to dissect out the pedicle for anastomosis, with rotational flaps the safest way to preserve the pedicle is to avoid dissecting it out, especially when performed by a non-microsurgery trained surgeon. The aim of our study will be to anatomically quantify where the 3 pedicles enter the anconeus muscle and how far it is safe to carry the dissection for use as a rotational flap

2. **Provide a description of the use of the anatomic material.** Identify the procedures to be performed and why they are required to be performed. The anatomic materials **cannot** be used for any purposes other than what is identified in this protocol. If there will be collaboration or if specimens will be used by other protocols, please identify the principal investigator and approved protocol number in which the specimens will be used.

We will dissect out each brachial artery of the specimen. We will then tie off the ulnar and radial artery distal to the medial collateral artery, recurrent posterior interosseous artery, and posterior branch of the radial collateral artery. This will force the epoxy into only the desired arteries. After ensuring all communicating branches are tied off, the epoxy will be forced into the specimen using positive pressure. This will be then given an opportunity to cure. Once cured, the anconeus will be dissected paying careful attention to where the pedicles enter the muscle. These pedicles will be measured and an analysis of the safe zone will be performed.

3. **List all the individuals** who will be involved in the use of the anatomic material and their role in this project. **Note:** All individuals participating in the use of anatomical specimens are required to sign a waiver acknowledging their understanding of the potential for exposure to certain contagious diseases. The waiver releases AGH/ASRI of any liability resulting from the handling of human anatomical specimens. A copy of the waiver is attached to this protocol. The principal investigator is responsible for obtaining signed waivers from all those participating in the protocol. The waivers should be submitted along with this protocol form. **The protocol will not be approved until waivers from all participating individuals have been received.**

Steven Regal, MD
R. David Graham, MD
Mark Carl Miller, PhD: supervise the experiment and data analysis
Victor Greco, MD: prepare specimens, run experiments
Alexander Kharlamov MD, PhD: assist run experiments

4. **Specimen Storage** (choose one):
Please identify how the specimens should be stored.
- frozen
 refrigerator
 other
- Specify duration of storage: 1 year

5. **Utilization.** Please indicate the location(s) in which the approved protocol will be conducted. (**Note:** If other than the Surgical Arts Center, specify method and route of transportation. **All** protocols being conducted in the Surgical Arts Center are to be coordinated through Amy Cupps, Manager, Preclinical Facilities, 412-359-6088.)

Location: Biomechanics Research Laboratory, Allegheny General Hospital

Transportation method and route: The tests will be run in the biomechanics laboratory, on 10th floor, South Tower, AGH, and in the 4th floor anatomy lab. The specimens will be moved on a cart from freezer room (02 level, South Tower) to the lab by freight elevator

Specify required dates and/or times specimen(s) are required: 07/01/2020

Additional requirements or information: No cause of death from cancer or dementia, no osteoporosis, under 65 yr.old, serology negative to HIV, Hepatitis C, Hepatitis B, no injuries or orthopaedic procedures on the arm and spinal cord.

6. **Disposal.** Expected disposal date: 07/01/2021

Note: *Principal investigators will be contacted to confirm the completion of the protocol prior to disposal of the specimens.*

WAIVER AND RELEASE

I understand that while at Allegheny General Hospital (AGH/ASRI), I may come in contact with cadavers, whole or partial anatomical specimens. I understand that I may have contact with a cadaver, which is infected with the Hepatitis B virus or HIV.

As a physician or other health care professional, I am aware of the means of transmission of infectious diseases, including the Human Immunodeficiency Virus (HIV) and agree that all possible precautions should be made to prevent any transmission of infectious disease including HIV. I further understand that some risk exists that such transmission is possible merely through the handling of tissues, and some of the tissues I will be handling in education activities may have been harvested from persons infected with HIV. Thus, to permit my participation in this activity, I agree to adhere to universal precautions when handling all tissues in this activity.

1. I will wear protective gloves at all times when handling tissues.
2. I will handle all tissues with care to avoid contact with my skin or mucous membranes.
3. I will observe extreme caution when using sharp instruments to avoid penetrating my or other's skin.
4. I will be aware that supplies for my protection are offered at AGH/ASRI.

I hereby release and hold harmless AGH/ASRI and its affiliates, and their respective directors, officers, staff, instructors, employees and agents from and against any and all causes of action, claims, demands, suits, cost liabilities, damages and fees (including attorneys fees) brought

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against any one or all of them based upon personal injury, disease, sickness, or death allegedly resulting from the handling of cadavers, tissues and other laboratory materials at AGH/ASRI.

Signature

Date

Please Print Name