Preferred Healthcare Incorporated

Simple Laceration Repair Using Topical Tissue Adhesives

PURPOSE:
To define clinical indications and procedures for wound closure using topical tissue adhesives (TTAs)

POLICY:
Preferred Healthcare Incorporated (PHI) physicians and nurse practitioners will utilize an evidence-based protocol for closing simple lacerations using TTAs.

The process for wound closure using TTAs is outlined in the PHI procedure manual under the title Simple Laceration Closure with Topical Tissue Adhesives.

Indications for wound closure using TTAs:
- Closure of easily approximated skin edges of wounds from simple, thoroughly cleansed, non-contaminated traumatic wounds caused by sharp trauma

Exclusion Criteria:
- Traumatic wounds over 24 hours old
- Wounds longer than 9 cm or greater
- Any wound with signs/symptoms of infection
- Wounds on mucosal surfaces or across mucocutaneous junctions (e.g. oral cavity, lips)
- Skin regularly exposed to body fluids
- Animal Bites or Human Bites
- Puncture or Crush Wounds
- Jagged or Stellate Wounds
- Wounds over high tension areas (e.g. joints)
- Patient allergy to Cyanoacrylate or Formaldehyde
- Wounds with gross contamination (e.g. soil, manure, gravel)

References:


Preferred Healthcare Incorporated
Originated: 01-15-2013
SIMPLE LACERATION CLOSURE WITH TOPICAL TISSUE ADHESIVES

Adapted, with permission, from web resources at The Royal Children’s Hospital, Melbourne, Australia (www.rch.org.au)

1. Perform hand hygiene and observe standard precautions

2. Rule out exclusion criteria:
   A. Traumatic wounds over 24 hours old
   B. Wounds longer than 9 cm or greater
   C. Any wound with signs/symptoms of infection
   D. Wounds on mucosal surfaces or across mucocutaneous junctions (e.g. oral cavity, lips)
   E. Skin regularly exposed to body fluids
   F. Animal Bites or Human Bites
   G. Puncture or Crush Wounds
   H. Jagged or Stellate Wounds
   I. Wounds over high tension areas (e.g. joints)
   J. Patient allergy to Cyanoacrylate or Formaldehyde
   K. Wounds with gross contamination (e.g. soil, manure, gravel)

3. Collect necessary supplies:
   A. Topical Tissue Adhesive (TTA) kit
      a. Contents: Dermabond or equivalent TTA, chux pad, 240 ml bottle of single use saline solution, 35 cc syringe with 18 gauge needle, 4x4 gauze pads for cleaning and drying skin around wound after irrigation

4. History and Physical
   A. Assess patients level of understanding about the injury, healability and risk factors
      a. Impact of patient’s current environment on patient’s ability to care for the wound
      b. Patient’s ability and motivation to comprehend and adhere to treatment plan
      c. Date of last tetanus injection
      d. Does the patient have an allergy to tetanus immunization
   B. Risk factors for wound healability
      a. Impaired nutritional status, low body weight, obesity, unplanned weight loss, appetite changes, cachexia and dehydration, and/or edema
      b. Medical conditions that interfere with healing (e.g. Diabetes Mellitus, PVD, Autoimmune Diseases, Cancer with Chemotherapy, Endocarditis)
      c. Medications that interfere with healing (e.g. NSAIDS, antineoplastics, systemic corticosteroids, anticoagulants)
Appendix F
Written Policy and Procedure

d. Tobacco History / Substance Use
e. Advanced Age 
f. Oxygenation status of skin and underlying tissue (e.g. COPD, CHF, anemia) 
g. Ability to mobilize and transfer

C. Physical Assessment

a. B/P, Heart Rate, Temperature, Respirations, LOC

D. Pain Assessment

a. Type, location, frequency and quality of pain occurring in the laceration
b. Pain severity using client self report, observation of nonverbal cues and/or a pain scale (e.g. Wong Baker FACES Scale, Visual Analog Scale)
c. Impact of pain on function
d. Differentiate between pain in the wound and in other areas

E. Assess integrity of underlying structures

a. Check capillary refill distal to the wound for vascular injury 
b. Check muscle strength and movement proximal and distal to the wound
c. Check for loss of function in proximal and distal tendons and ligaments
d. Check for sensation surrounding the areas
   1. For hand/finger lacerations check 2-point and sharp/soft discrimination on the area distal to the wound and distal extremities 
e. Check for boney involvement 
f. Check the surrounding area for foreign bodies

F. History of the laceration

a. Where patient would have gone if service not provided at this facility 
b. Patient’s experience of injury 
c. Mechanism of injury
d. Wound contact contaminates (e.g. manure, rust, soil)
e. Time elapsed since injury 
f. Amount of blood loss

G. Wound Assessment

a. Length, width, and shape of wound 
b. Location 
c. Wound depth 
d. Appearance of wound bed 
e. Amount and type of exudates 
f. Presence of odor after cleaning 
g. Description of wound edges 
h. Presence of foreign bodies in the wound or surrounding tissue 
i. Determine the need for tetanus prophylaxis (Appendix A)

H. Immediate Referrals to Emergency Department

a. Suspicion of injury to blood vessels, muscles, tendons or nerves 
b. Suspicion of boney involvement or an open fracture

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c. The laceration is extensive or of unknown depth (e.g. deep puncture wound)
d. Wounds in which hemostasis cannot be achieved
e. There is a possibility that the laceration transects the joint capsule
f. There is strong suspicion of a foreign body in the wound or surrounding tissue
g. There is concern about the cosmetic outcome
h. Wounds meeting other exclusion criteria

5 Applying TTAs

A. Wash your hands and observe standard precautions
B. Don clean gloves
C. Irrigate wound with sterile normal saline using a 35 ml syringe with an 18 gauge needle
   Irrigate with 30 ml to 60 ml of normal saline per cm of wound length
D. Use 4x4 gauze soaked in normal saline to clean skin around wound
F. Pat dry with clean 4x4 gauzes
G. Appose wound edges
F. Crush TTA vial
H. Invert vial to saturate sponge tip
I. Gently brush adhesive over laceration (Do not get adhesive in wound bed)
J. Avoid pushing adhesive into wound
K. Continue to firmly appose wound edges for 2 minutes to allow adhesive to dry
L. Repeat I – K for a total of 3 layers
M. After adhesive has dried, may apply a clean dry dressing if patient prefers

6. Home Care Instructions

A. Care of the wound
   a. Keep area dry for 48 hours
   b. May shower after 48 hours; area over wound should be patted dry
   c. Do not use antibiotics creams, lotions, or petroleum jelly over wound
   d. Adhesive will slough off in 5 to 10 days

B. Return to the clinic for the following signs and symptoms
   a. Wound reopens
   b. Fever, Redness, Edema, or increased pain develops
   c. If the areas below the wound becomes numb, painful, or tingles

C. Pain Control
   a. Use age appropriate dose of over the counter acetaminophen unless contraindicated
### Appendix A: Tetanus Prophylaxis for Clean Minor Wounds

<table>
<thead>
<tr>
<th>History of Tetanus Immunization</th>
<th>Td or Tdap</th>
<th>Tlg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertain of &lt; 3 doses of immunization series</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>≥ 3 doses received in an immunization series less than 10 years ago</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>≥ 3 doses received in an immunization series more than 10 years ago</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Td – Tetanus and diphtheria toxoid combined  
Tdap – Tetanus, diphtheria, and acellular pertussis toxoids combined  
Tlg – Tetanus Immune Globulin
References


TOPICAL TISSUE ADHESIVES PRE-TEST / POST-TEST

Directions: Circle your answer choices to the following questions:

1. Which of the following wounds would be most suitable for closure using topical tissue adhesives?
   A) A 10 cm wound located on the lower leg, which occurred 2 days ago
   B) A 5 cm wound located on the forearm, which occurred 6 hours ago
   C) A jagged wound located over the right knee, which occurred 12 hours ago
   D) A stellate wound located on the left thigh, which occurred 1 hour ago

2. During your assessment of a patient presenting for simple laceration repair, the patient reports his last tetanus booster was 7 years ago. Following the CDC recommendation to prevent tetanus, what action should you take before the patient is discharged?
   A) Administer Td injection before discharge
   B) Administer Td and TIG before discharge
   C) Administer TIG before discharge
   D) Do nothing; the patient is up to date on his tetanus immunization

3. Following evidence-based practice, which of the following statements is true when irrigating a simple laceration?
   A) Irrigate wounds using sterile water
   B) Irrigate wound using a 20 ml syringe
   C) Irrigate wound using an 18 g needle
   D) Irrigate wound with 10 ml of solution per centimeters in length

4. Sterile gloves are required for all laceration repairs?
   A) True
   B) False

5. When doing a simple laceration repair using topical tissue adhesives, how long should the wound edges be manually apposed to allow the adhesive to set?
   A) 30 seconds
   B) 1 minute
   C) 90 seconds
   D) 2 minutes
TOPICAL TISSUE ADHESIVES PRE-TEST / POST-TEST (continued)

6. Which of the following is not a benefit of using topical tissue adhesives when compared to suturing?

A) Decreased rate of wound dehiscence
B) Comparable rates for post-wound infection
C) Better cosmetic appearance of scar
D) Preferred method of closure by parents and healthcare providers

7. How many traumatic wounds are treated in the emergency department annually?

A) 3 million
B) 6 million
C) 9 million
D) 12 million

8. Most traumatic wounds can be treated safely in non-emergent settings?

A) True
B) False

9. When assessing a laceration, which of the following should be assessed?

A) How, when, and where the wound happened
B) The length, width, and depth of the wound
C) Presence of underl Ine major vascular damage
D) All should be included

10. When should a patient return to the clinic for removal of adhesive after closing a wound with topical tissue adhesive?

A) 5 days – 7 days
B) 8 days – 10 days
C) 11 days – 14 days
D) No follow-up is needed for adhesive removal
Topical Tissue Adhesives
As An Alternative to Suturing
In Non-Emergent Healthcare
Settings

Presented by:
H. Anthony Couch
BA, MSN, APRN

Part I:
Introduction

- 7 Million Traumatic Wounds / Year seen in ED
- Account for approximately 10% of ED visits
- Most wounds are simple lacerations which could be treated safely in non-emergent settings
- Suturing has been the traditional method for closing wounds

What Are Topical Tissue Adhesives?
(TTAs)

- Sterile, liquid adhesives composed of a cyanoacrylate monomer
- FDA approved for human use
  - 2-Octyl Cyanoacrylate (1998)
    - Dermabond
  - N-Butyl-2 Cyanoacrylate (2002)
    - Indermal
### Advantages of TTA vs. Sutures

<table>
<thead>
<tr>
<th>TTA</th>
<th>Sutures</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Maximum bonding strength at 2.5 minutes</td>
<td>- Equivalent in strength to healed tissue at 7 days post repair</td>
</tr>
<tr>
<td>- No sharps</td>
<td>- Requires needles</td>
</tr>
<tr>
<td>- Usually no anesthesia is needed</td>
<td>- Requires anesthetic injection</td>
</tr>
<tr>
<td>- Faster repair time</td>
<td>- 7 to 10 day healing time</td>
</tr>
<tr>
<td>- Preferred by Patients</td>
<td>- Patients more apprehensive or fearful of procedure</td>
</tr>
<tr>
<td>- No Follow-up Visit to remove</td>
<td>- Follow-up visit required for removal</td>
</tr>
<tr>
<td>- Water and bacteria resistant covering</td>
<td>- Must avoid water exposure</td>
</tr>
</tbody>
</table>

### Part II: Assessment

**History**
- Past Medical History
- Tetanus Immunization Status

**HPI**
- Mechanism of Injury
  - Shear
  - Crushing
  - Puncture
  - Abrasion

- When? Where? How?

### Part III: Physical Exam

- Hemeostasis
- Neurovascular Status
- Deep Structure Involvement
- Foreign Bodies
- Contamination
- Undermining
- Wound Bed
- Tension
  - Low Tension wound = less than 5 mm gap
  - Greater than 5mm gap = dermal suturing needed
Measuring the Wound
Length x Width x Depth

- Length in Centimeters
  Longest point on wound measured from head-to-toe
- Width in Centimeters
  Widest point on wound: measured from side-to-side
- Depth in Centimeters
  Measure by inserting gloved finger or tip of sterile cotton swab

Part IV:
Preparing the Wound

- Clean area around wound with mild soap and water
- Irrigate Wound
  Ideal pressure 8-12 psi
  Use 35cc syringe with saline
  Use 60cc/cm of wound length
  For Most Wounds, Tap Water as Effective as Saline

Part V:
Is the Wound Suitable for TTA

Exclusion Criteria:
- Traumatic Wounds over 24 Hours Old
- Infected Wound
- Wounds on Mucosal Surfaces
- Wounds across Mucocutaneous Junctions
- Bites
- Puncture or Crush Wounds
- Jagged or Stellate Wounds
- Wounds Over High Tension Areas (Joints)
- Allergy to Cyanoacrylate or Formaldehyde
Part VI: Applying TTA

- Dermabond Application
  
  (1) Clean wound and establish hemostasis. Be sure wound edges and surrounding skin are dry.
  
  (2) Crush vial by applying pressure at the midpoint of the ampule. Gently squeeze to express the liquid through the applicator tip.
  
  (3) Position wound in a horizontal plane to prevent run-off. Manually approximate the wound edges. Gently brush on a thin layer of liquid to the wound edges while maintaining proper eversion of skin edges. The adhesive should extend at least ½ centimeter on each side of the apposed wound edges.

Part VII: Home Care Instruction

After TTA Application

- Keep it dry
- Okay to shower but do not soak wound
- After shower, pat area dry
- Avoid swimming until wound is healed
- No ointments or creams over area
- Do not scratch, rub or pick at wound
- Avoid sun exposure to wound
- TTA will fall off within 7 to 14 days
- Follow-up for increased pain, redness, or drainage from wound or if wound reopens

Questions?
Appendix H

PowerPoint Slides

References

Appendix 1

Competency Check-off Form

Wound Closure with Topical Tissue Adhesive

The wound closure with topical tissue adhesives competencies must be completed prior to use of this service at Preferred Healthcare Inc.

<table>
<thead>
<tr>
<th>Education Session</th>
<th>Date Reviewed</th>
<th>Proficiency Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Read Policy and Procedure</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Attend Powerpoint Presentation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Check-Off</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Aseptic Technique</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Addresses need for Tetanus Prophylactic</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• HPI</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Physical Exam</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Treatment Procedures</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Verbalizes aftercare instructions</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Verbalizes indications for referral</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Documented Procedure</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

I am ____ am not ____ comfortable this provider has satisfactory completed the wound closure with topical tissue adhesive competency testing.

Participant’s Assigned Color ___________________________ Date: __________

If not comfortable with this provider’s ability to meet the objectives, please note the items needing supervisory oversight and retesting:

________________________________________________________________________

________________________________________________________________________
<table>
<thead>
<tr>
<th>Participant Documented History of Present Illness</th>
<th>Date Reviewed</th>
<th>Proficiency Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Wound location</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Time of injury</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Cause of injury</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Pain assessment</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Pertinent Past Medical History</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

| Participant Documented Pertinent Past Medical History            |               |                      |
| • Patient’s Allergy confirmed                                   | Yes           | No                   |
| • Past Medical History Reviewed                                 | Yes           | No                   |
| • Addressed need for Tetanus Prophylactic                       | Yes           | No                   |

| Participant Documented Wound Assessment                          |               |                      |
| • Vital Signs Recorded (B/P, HR, Respirations, LOC)              | Yes           | No                   |
| • Wound length, width, and depth                                | Yes           | No                   |
| • Hemeostasis Achieved                                          | Yes           | No                   |
| • Neurovascular Status Checked                                  | Yes           | No                   |
| • Assessment of surrounding Tissue                             | Yes           | No                   |
| • Recognized Inclusion / Exclusion Criteria                     | Yes           | No                   |

| Participant Documented Procedure                                 |               |                      |
| • Wound cleaned with normal saline using 35 ml syringe with an 18 gauge needle (30 ml per cm of wound length) | Yes           | No                   |
| • Skin around wound cleaned and patted dry before adhesive applied | Yes           | No                   |

| Participant Documented Aftercare Instructions                    |               |                      |
| • Keep wound Dry                                                | Yes           | No                   |
| • Return for Signs and Symptoms of Infection                    | Yes           | No                   |

| Participant Documented Where Patient Would Have Sought Treatment if service was not provided at Location | Yes           | No                   |

Participant’s Assigned Color ________________________________
Appendix K

Letter of Institutional Commitment

Preferred Healthcare Incorporated

686 South Highway 25W
Williamsburg, KY 40769
Phone: (606) 549-5052
Fax: (606) 549-2718
ednamoses@hotmail.com

January 15, 2013

Chatham University
Institutional Review Board
Woodland Road
Pittsburgh, PA 15232

Dear IRB members:

This letter is to confirm our commitment at Preferred Healthcare Incorporated to the capstone project Simple Laceration Repair: Using Topical Tissue Adhesives in Primary Care. The healthcare providers and clinical staff have met with the project implementer, H. Anthony Couch, to discuss the project and to discuss how adding this service could benefit the rural community that we serve. The providers and staff are in agreement to work collaboratively with Mr. Couch to implement this service.

It is understood that no part of this project can begin before the project has approval by the IRB and cannot begin before the first day of NUR 799. Mr. Couch anticipates this project to pilot over a period of 12 to 14 weeks. Please feel free to contact me if you have further questions or concerns.

Sincerely,

Edna Moses
MSN, APRN, NP-C
Appendix L

HIPAA WAIVER REQUEST

Institutional Review Board
IRB Submission and HIPAA Waiver Request

This form must be completed for every medical record chart review or clinical database review that will be conducted for evidence-based practice purposes. This includes the review of office or clinic charts and retrospective or prospective chart and database reviews. This form serves as a HIPAA waiver request for evidence-based practice.

1. Project Implementer
   Name: Herbert Anthony Couch
   Academic Program or Department: DNP
   Electronic Mail Address: bcouch@chatham.edu
   Signature: [Signature]
   Date: 01-29-2013

2. Faculty Project Advisor (if applicable):
   Name: Michelle Doas
   Highest Degree: Ed.D.
   Discipline of Highest Degree: Education Doctorate
   Signature: [Signature]
   Date: 1-30-13

3. Other project implementers (include names, degrees, and programs or departments) NA

4. Title of evidence-based project: Simple Laceration Repair: Using Topical Tissue Adhesives in Primary Care

5. Is this a federally funded grant? If so, and if this protocol is or will be used to certify human subjects in any federally funded grant, please submit the entire grant application as appendix materials along with this form. NO

6. Check the type of record/chart/database that will be reviewed for evidence-based practice purposes.
   - [X] Medical Records or Chart Reviews
   - [ ] Films/X-rays
   - [ ] Computer Database(s)
   - [ ] Hospital administrative or billing records
   - [ ] Quality Improvement Records
Appendix L

HIPAA WAIVER REQUEST

___ Pathology or Laboratory Reports
___ Other types of record, specifically:

7. For individual(s) who will be responsible for querying medical records/charts/database(s), give
   Name: Herbert Anthony Couch
   Affiliation: Chatham University DNP student (clinical site)
   Precise Role on Project: Project Implementer

8. For additional individuals who will be given access to the data, give
   Name: Michelle Doas
   Affiliation: Chatham University
   Precise Role on Project: Faculty Advisor

9. Brief description of the purpose of the evidence-based practice project:
   
   **Purpose:** This project was designed to utilize evidence-based practice to broaden access to healthcare services in a rural primary care clinic by adding a new service, simple laceration repair using topical tissue adhesives (TTAs).

   **The objectives for the project are as follows:**
   
   (1) Develop a simple laceration repair evidence-based guidelines adapted for use in a primary care setting,
   
   (2) Educate providers on the use of TTAs,
   
   (3) Implement guidelines for simple laceration repair using TTAs at a primary care clinic
   
   (4) Evaluate adherence to the implemented guidelines by do a prospective patient chart review.

10. Number of subjects that will be involved or number of database records that will be reviewed:

    Since injuries are not predictable, the number of charts reviewed cannot be determined at this time. Only those patients presenting for simple laceration repair who meet the inclusion criteria for TTA use will be reviewed.

11. Time period over which data is to be obtained:

    12 – 14 WEEKS (05-06-2013 – 08-05-2013)

12. Data is to be used for:

    ___ Publication
    ___ Oral Presentation
    ___ Subsequent specified research, specifically:
    ___ Possible future research (e.g. database creation that may suggest research lines not presently anticipated) for which IRB approval will be needed.
    ___ Other, specifically: Quality improvement and outcome measures
Appendix L

HIPAA WAIVER REQUEST

_X_ Other, specifically: Quality improvement and outcome measures

13. Categories of data that will be obtained during the review:
   ___ Diagnosis
   ___ Lab values
   ___ Demographics (age, sex, address)
   ___ Radiology testing
   ___ Length of stay
   ___ Drug/Device utilization
   ___ Procedure/Treatment
   ___ Clinic Notes
   ___ Location of Service (OR, ER, In/Out, PT)
   ___ Billing/Charges
   ___ Provider of Record
   ___ Confirmative Lab Value
   ___ Other, specifically:

14. The following information is considered identifiable under the HIPAA Privacy Rule regulations. Please check off whether any of the following will be obtained:
   ___ Participant Name
   ___ Participant Street Address
   ___ Participant town or city
   ___ Participant State Address
   ___ Participant Zip code Address
   ___ Dates of treatment that is more specific than the year.
   ___ Participant telephone number
   ___ Participant fax number
   ___ Participant electronic mail (email) address
   ___ Participant Social Security Number
   ___ Participant medical record number
   ___ Participant health plan number
   ___ Participant account numbers
   ___ Certificate or license numbers
   ___ Vehicle identification numbers
   ___ Medical Device Identifiers
   ___ Internet Protocol (IP) address
   ___ Web URLs
   ___ Biometric identifiers
   ___ Full face photographs
   ___ A unique identifying number, characteristic or code, specifically:

If none of the above items will be recorded, please check the following line: ___x__

15. If links to identifiers are used, please describe the coding mechanism.
Appendix L

HIPAA WAIVER REQUEST

Each of the two participating providers will be assigned a color code (Red or Blue). Only the project implementer will know which color is associated with the provider. A chart audit tool has been designed to collect data on the participants. The only patient charts to be reviewed are those presenting for simple laceration repair at Preferred Healthcare Inc. The participant will be asked to retrieve the chart for review.

16. Investigators are required to obtain only the minimum data necessary in order to achieve the goals of the evidence-based practice project. Please justify why the data you are obtaining are the minimum necessary to achieve the goals of the evidence-based practice project.

The project implementer will need to gather data on number of procedures completed. Procedure notes will need to be reviewed for quality improvement.

17. Federal regulations require that all human research subjects provide informed consent and authorization to use protected health information, including medical records and chart and database reviews. The IRB is allowed to waive this requirement for subject consent and authorization. If you wish to request a waiver of informed consent and/or a waiver of HIPAA authorization, please provide the following justifications.

   a. The proposed use of these data/documents/records presents no more than minimal risk to the privacy of the individual because: the charts will be reviewed by the project implementer for the purpose to identify themes for areas of improvement or need for further training.

   b. The research could not practicably be conducted without the waiver of consent and authorization because: The clinic is staffed daily by a sole provider. Although the project implementer will be involved in the procedures on the day he is there, he has no justifiable reason to review the charts of other providers who will also be involved in the project.

   c. The research could not practicably be conducted without access to and use of protected health information because: Access to patient records is needed to determine how often the service is being used.

18. Please describe the steps taken to assure privacy, confidentiality, and security of subject data.

Use of the guidelines will be self-reported by the provider to the project implementer on the day following the procedure. A chart review will be conducted to document adherence to the guidelines. Provider or patient information will not be recorded, thus maintaining the confidentiality of the provider and patient.

19. Will data be sent outside Chatham University? ___ Yes ___ No

   If yes:

20. You are required to destroy identifiers (or links) at the earliest possible time. Please describe your plans and specify when this will occur.
Appendix L

HIPAA WAIVER REQUEST

(If there is a justification for retaining the identifiers, please provide this information.)

The chart audit tools will be kept for 1 year after the project completion date then shredded. Only the project implementer and faculty adviser will have access to this information.