MEMORANDUM FOR ST

ATTN: CAPT RENFORD CINDASS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled *A Novel Biodegradable, Biointegratable, and Biocompatible Dressing for NPWT* presented at/published to *Association of Surgeons Great Britain and Ireland 11-13 May 2016* with MDWI 41-108, and has been assigned local file #16193.

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

Warrior Medics – Mission Ready – Patient Focused
1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study (e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SC5 O&M); GSE R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRP); NIH; Congressionally Directed Medical Research Program (CDMRP); Grants; etc.)
   b. In Section 2, there may be funding available for journal costs. If your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g., case report, OVAL study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title, sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CD for processing (59crdpubspres@us.af.mil). If you have any questions or concerns, please contact the 59 CRD Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). See 59 MDW 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DOD 3218.02_AFP 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 43-401 LP:
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."
Evaluation of a Novel Biodegradable/Biodegradable Negative Pressure Wound Dressing Sponge in a Porcine Model (Sus scrofa domestica)

A Novel Bioresorbable, Biodegradable, and Biocompatible Dressing for NPWT

Funding received for this study: Yes

Do you need funding support for publication purposes: No

Is this material classified?: No

Material is for: Domestic release

Publication information:

11a. Publication Journal: (List intended publication/journal)

11b. Published Abstract: (List intended journal)

11c. Poster: (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

11d. Platform Presentation: (At civilian institution: name of meeting, state, and date of meeting.)

Association of Surgeons of Great Britain and Ireland/ 11-13 May 2016

OTHER: (Describe: name of meeting, city, state, and date of meeting.)

Expected date when you will need the CRD to submit your cleared presentation/publication to DTIC:

May 10, 2016

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Grad/Rank: O-3

Squadron/Group/Office Symbol: 59MDW ST RESTOR

Institution (If not 59 MDW):

UPitt

Certify that any human or animal research related studies were approved and performed in strict accordance with 32 CFR 216, AFMAN 41-40-1, JP, and 59 MDW 41-108. I have read the final version of the attached material and certify that it is an accurate manuscript for publication and/or presentation:

Raul S. raul.s.corpus.ctr@mail.mil

April 26, 2016

Michael R. Davis, Lt Col, Director-RESTOR, Deputy Commander

April 26, 2016
The presentation is approved. This should receive a legal ethics review since it will be presented to a foreign audience.
A Novel Bioresorbable, Biointegratable, and Biocompatible Dressing for NPWT

CPT Renford Cindass Jr., MD
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Lt Col Michael R. Davis, MD, FACS
RESTOR Program
Deputy Commander, USA Institute of Surgical Research
59MDW Science and Technology
Disclaimer

The views expressed are those of the authors and do not reflect the official view or policy of the Department of Defense, Department of the Army, Department of the Air Force or its Components.

The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended.

Project was funded through the US Air Force Medical Support Agency, coordinated through and managed by the 59MDW Office of Wing Chief Scientist, Science and Technology.
Negative Pressure Wound Therapy

- Developed in 1997
- Mechanisms
  - Thermoregulation and moisture retention
  - Drainage of exudate and inflammatory mediators
  - Optimization of the wound bed
  - Microdeformation
  - Macrodéformation
Limitations of Polyurethane Sponge

- Dressing changes every 2-3 days
- Occasionally painful for the patient
- Macrodéformation causes wound contraction

Goals for the Ideal Sponge

- Bioabsorbable to prevent dressing changes
- Provides a scaffold to fill the defect
- Minimize wound contraction
- Accelerate granulation tissue formation
Our Sponges

- Bioresorbable, biointegratable, and biocompatible sponge
  - Polycaprolactone (PCL)
    - A biodegradable polyester
    - Used in Monocryl™ suture (Ethicon)
  - 2 different manufacturing processes
    - Synthesized from a 25%/75% PCL/chloroform solution
    - 3D printed scaffold
  - PCL is inherently hydrophobic
    - Treated with different agents to make the sponge hydrophilic
      - Sodium hydroxide
      - Polydopamine
      - Polydextrose
Pilot Study Design

- Growth Control
- Polyurethane Sponge
- PCL NaOH Sponge
- 3D Printed PCL Polydextrose Scaffold
- Wet-to-Dry Dressing
- Untreated PCL Sponge
- PCL Polydopamine Sponge
Hydrophilic Sponges

PCL NaOH

POD 12

POD 15

POD 18

PCL Polydopamine
Results

Area of Granulation Tissue

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<th>POD</th>
<th>WTD</th>
<th>Polyurethane</th>
<th>PCL NaOH</th>
<th>PCL Polydopamine</th>
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</table>
Results

Percentage of Wound Contraction

- WTD
- Polyurethane
- PCL NaOH
- PCL Polydopamine

Percent Area Contraction

POD0, POD3, POD6, POD9, POD12, POD15, POD18, POD21, POD24, POD27, POD30
Conclusions

- A bioresorbable, biointegratable, and biocompatible sponges
  - Potentially obviate the need for dressing changes by providing a scaffold for cellular ingrowth
  - Minimize wound contraction
Future direction

- Expand the study to assess the PCL sponges treated with NaOH and polydopamine
- Pathology assessment with immunohistochemical staining
- Larger wounds