MEMORANDUM FOR SGOM
ATTN: CAPT JEAN STOREY

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled *Six Years Experience with Porcine Extracellular Matrix: A New Paradigm for Pelvic Floor Repair* presented at/published to ACOG Annual Clinical Meeting, La Jolla, CA, 6-9 May 2017, in accordance with MDWI 41-108, has been approved and assigned local file #17171.

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 at the Chief Scientist’s Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.

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*
INSTRUCTIONS
USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

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) (SGS O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); 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, QA/QI 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.

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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.

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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"

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"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."
1. TO: CLINICAL RESEARCH
2. FROM: (Author's Name, Rank, Grade, Office Symbol)
   Jean Storey, Capt, O3, SGOM
3. GME/GHSE STUDENT: YES NO
4. PROTOCOL NUMBER: N/A
5. PROTOCOL TITLE: (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.)

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6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
   Six Years Experience with Porcine Extracellular Matrix: A New Paradigm for Pelvic Floor Repair

7. FUNDING RECEIVED FOR THIS STUDY? YES NO
8. FUNDING SOURCE:
9. IS THIS MATERIAL CLASSIFIED? YES NO
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? YES NO

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12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC

   DATE
   15 Apr 2017

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)
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14. DUTY PHONE/PAGER NUMBER
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15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

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   c.
   d.
   e.
   f.

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 IP, 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.

16. AUTHOR'S PRINTED NAME, RANK, GRADE
    Jean Storey, Capt, O3

17. AUTHOR'S SIGNATURE

18. DATE
    01 Apr 2017

19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE
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20. APPROVING AUTHORITY'S SIGNATURE

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    01 Apr 2017

59 MDW FORM 3039, 20160218 PREVIOUS EDITIONS CURRENTLY IN USE CAN BE USED ALL OTHERS ARE OBSOLETE
Research presentation with determination from SAMMC IRB as case series report. AIO notified of protest, but in accordance with local policy presentation is cleared. Appropriate disclaimers included.
Six Years Experience with Porcine Extracellular Matrix: A New Paradigm for Pelvic Floor Repair

Jean V Storey, DG, Capt, USAF, MC; Scott Kaminski, DO, COI, MC, USA; Rahul Yordan-Jovet, MD, LtCol (Ret), USAF, MC

San Antonio Uniformed Services Health Education Consortium, TX

BACKGROUND

- Pelvic organ prolapse (POP) can be associated with sexual, defecatory, and urinary dysfunction
- 3rd most common reason for hysterectomy and an 11% lifetime-risk of surgery for POP
- 30% re-operation after initial surgery
- Native tissue augmentation includes synthetic mesh or biologic-derived graft which can increase durability and longevity of repair
- Significant complications including dyspareunia, contractions, erosions and fistulas appear material-dependent

Tissue Augmentation Options

<table>
<thead>
<tr>
<th>SYNTHETIC (Permanent)</th>
<th>Encapsulation or Integration</th>
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<tr>
<td>Xenograft (porcine)</td>
<td>Absorbable (constructive remodeling)</td>
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<th>BIOLOGIC</th>
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<td>Allograft (human)</td>
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Porcine Extracellular Matrix

![Figure 1 - Package](image1)

![Figure 2 - Placement](image2)

Methods

- Case Series
  - 64 patients with Porcine Extracellular Matrix
  - Variety of level 1 and 2 defects

Outcome

- Support (POP-Q @ 3 mos)
- Durability of repair (POP-Q yearly)
- Intra / Postoperative complications

Charts at our institution between 2010-2015 were reviewed.

Preoperative POP-Q scores measuring level 1 and level 2 support ranged from -2 to +6 at most presenting part.

Total of 93 pelvic reconstruction procedures performed:

- 61 anterior repairs
- Includes 17 TVHs with uterosacral ligament suspension and 6 concurrent posterior repairs
- 30 additional posterior repairs
- 27 vaginal paravaginal repairs
- 8 bilateral sacrospinous colpopexies

RESULTS

- POP-Q scores obtained from 3-72 months (median = 54) postoperatively
- Durable global level 1 and 2 support with most patient at -3 scores at presenting part
- No significant surgical or product complications were identified
- Postoperative
  - 2 anatomical failures to anterior or apical scores of -1 at most presenting part
  - Only 1 symptomatic case needed reoperation (enterocele)

CONCLUSION

- Porcine Extracellular Matrix
  - Is technically easy to use
  - Provides durable POP repair
  - No complications associated with matrix
  - No host-grait rejection

Limitations

- Observational case series
- No controls or randomization

Future Directions

- Prospective trial comparing autologous and absorbable xenograft repairs
- QoL evaluation
- Cost-effectiveness evaluation

*The views expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of the United States Air Force, Department of the Army, or Department of Defense or the U.S. Government.*
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