



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

27 APR 2016

MEMORANDUM FOR AFMOA/HCE

ATTN: ELSA CAMOU/ COL MARK PACKER

FROM: 59 MDW/SGVU

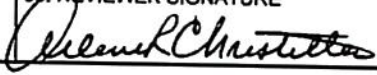
SUBJECT: Professional Presentation Approval

1. Your paper, entitled **HCE Research Coordination Directorate (ReCoord Database)** presented at/published to **DHA Public Health Subcommittee Report** with MDWI 41-108, and has been assigned local file #**16154**.
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 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

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

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Mark Packer, Col, AFMOA/HCE	3. GME/GHSE STUDENT: ☐ YES ☒ NO	4. PROTOCOL NUMBER:
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.)			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: HCE Research Coordination Directorate (ReCoorD Database)			
7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO			
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 NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☒ FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
☐ 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 institutions: name of meeting, state, and date of meeting.)			
☒ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) Materials will be used in the DHA Public Health Subcommittee Report.			
12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).			
DATE As soon as possible			
13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Camou, Elsa, elsa.camou.1.ctr@us.af.mil			14. DUTY PHONE/PAGER NUMBER 210-292-7324
15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Mark Packer	Col	AFMOA/Hearing Center of Excellence	AFMOA
b.			
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 Packer, Mark Col		17. AUTHOR'S SIGNATURE PACKER.MARK.D.1157650285 Digitally signed by PACKER.MARK.D.1157650285 DN: cn=PACKER.MARK.D.1157650285, o=AFMOA, ou=AFMOA, email=PACKER.MARK.D.1157650285@us.af.mil, c=US	18. DATE
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Packer, Mark Col		20. APPROVING AUTHORITY'S SIGNATURE PACKER.MARK.D.1157650285 Digitally signed by PACKER.MARK.D.1157650285 DN: cn=PACKER.MARK.D.1157650285, o=AFMOA, ou=AFMOA, email=PACKER.MARK.D.1157650285@us.af.mil, c=US	21. DATE

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1st ENDORSEMENT (59 MDW/SGVU Use Only)			
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED 4/5/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16154	
24. DATE REVIEWED 15 Apr 2016	25. DATE FORWARDED TO 502 ISG/JAC		
26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. ☐ N/A			
27. COMMENTS ☒ APPROVED ☐ DISAPPROVED I called the number provided but it would not leave a message and asked me to try again later. Your info on slide #8 regarding the VA not using RePorter is incorrect. The reason the DoD HA has mandated information to go to RePorter is based on a GAO 2012 report and based on that GAO report the VA is on RePORTER. If you wish I can send you the VA slides on the NIH RePORTER so you have their information in case you are questioned by anyone from the VA.			
28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER COL LINDA STEEL-GOODWIN, USAF, BSC	29. REVIEWER SIGNATURE STEEL GOODWIN LINDA. 1188483583		30. DATE April 15, 2016
2nd ENDORSEMENT (502 ISG/JAC Use Only)			
31. DATE RECEIVED 18 April 2016	32. DATE FORWARDED TO 59 MDW/WA		
33. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED Slide poster presentation includes the disclaimer required by the Joint Ethics Regulation. There are no ethics issues with making this presentation.			
34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Arlene R. Christilles, GS-14, Chief, Civil Law	35. REVIEWER SIGNATURE 		36. DATE 20 Apr 16.
3rd ENDORSEMENT (59 MDW/WA Use Only)			
37. DATE RECEIVED 21 April 2016	38. DATE FORWARDED TO 59 MDW/SGVU 26 April 2016		
39. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED			
40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Christopher Carwile, TSgt/E-6, NCOIC, PA	41. REVIEWER SIGNATURE CARWILE CHRISTOPHE R.STEWART.1280477229		42. DATE 26 April 2016
4th ENDORSEMENT (59 MDW/SGVU Use Only)			
43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE		
45. COMMENTS ☐ APPROVED ☐ DISAPPROVED			
46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE		48. DATE

DEPARTMENT OF DEFENSE
HEARING CENTER OF EXCELLENCE

HCE Research Coordination
Directorate
(ReCoord Database)

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

PURPOSE/RATIONAL

- Research project management ought to be considered an essential part of any effort, by departmental administrator and funding sponsor alike.
- Auditory portfolio management is often hidden within broader mission scopes and visibility into those portfolios is often limited at best.
- Current specialty-specific tracking databases do not exist
- Current broad-sweeping portfolio management tools do not exist (not true – define terms?)
- The HCE receives requests from a variety of oversight bodies for reports on the current state of “project-through-portfolio” efforts.
- Tools such as NIH’s eReporter, while still in development, do not yet appear to meet HCE element requirements.

HCE TASKS

- Create a simple (Access) database to track, quantify and report on the auditory vestibular portfolio across the DOD
 - HCE HQ, Database Engineer will provide IT/IM support
- Execute MOAs as requested by sites in the Collaborative Auditory Vestibular Research Network (CAVRN). Efforts to be conducted by already embedded HCE Regional Coordination Team (RCT) members.
 - Site Identifiable Information (SII) definition and handling instructions. Site-specific data may only be shared by HCE in an unidentified format (shared in DoD-wide/aggregate), unless shared with specific awareness and approval from said site.
 - MOA for each site defines HCE RCT responsibility and accountability for the data and its usage
 - **MOA is optional based on site preferences**

ACCESSIBILITY/PROTECTION

- Access will be limited to the Regional Research Coordinator at each site and HCE HQ, with each RCT member populating only their location's version of the database back-end file.
- Data from each location will be uploaded to a central HCE database on a regular basis monthly
 - HCE database administrator marries all backend files to one master HCE file, cleans any duplicates or errors and send regional team members back their own single-site back-end file to continue populating.
- RCT members will never see their counterparts' files.

REPORTING

- Reports collating data points for overview-level information dissemination will be generated by HCE HQ.
- Proprietary information or collected **study data** will never be included in ReCoord
- **Reporting capability examples:**
 - Descriptive categorical data
 - e.g., # “Diagnostic,” # “6.2”, or # “TRL 4” Tinnitus projects started/completed in FY15, etc.)
 - Economic Data:
 - e.g., total FY dollars applied for in intramural/NIH/NSF/VA/etc. grant funding vs. total awarded
 - These figures may be reported by category but not by site (i.e., \$10M Diagnostic or \$10M 6.2 PE projects or \$10M TRL 4 projects, etc.)
 - Site administration tools such as event dates approaching, including conference abstracts, grant submission and reporting, and annual IRB review deadlines.
 - Increases in collaboration, interdisciplinary make-up, success rates, translational pathways, gaps analysis, etc.

INFORMATION COLLECTED

NIH eReporter

Projects: title, description, start/end date

Persons: name, degrees, phone numbers, email

Organizations: grant-recipient organization only

CRADA/ MOAs : not reported

Data Sources: not reported

Grants/Proposals: ID#, funding agency, funding mechanism, award amount, award type, activity code

IRB: not reported

Protocol: clinicaltrials.gov ID#

Analysis not reported

Dissemination: publications found in PubMed and patents

ReCoord

Projects: title, description, category (e.g., diagnostic, prevention, rehabilitation), relevance to other injuries (e.g., TBI, PTSD)

Persons: name, degrees, requirements (i.e., CITI training), phone numbers, email

Organizations: all engaged or collaborating

CRADA/MOA/MOU: Start date, ID #, parties, \$ value, status, execution & expiration dates

Data Sources: list of all data sources used, Data Sharing Agreements information (Start date, ID #, parties, \$ value, status, execution & expiration dates)

Grants/Proposals: ID#, funding agency, funding mechanism, submission date, award amount, award date

IRB: name of IRB, scientific reviewer, approval/renewal /closure dates

Protocol: title, start/end dates, subject target count, current enrollment, clinicaltrials.gov ID# if applicable

Analysis status

Dissemination: patents, publications, presentations, posters, reports

NIH RePORT

- All current grants funded by VA, NIH, and other non-DoD federal agencies (mandatory reporting)
- Information on grant-associated products including publications and patents for NIH grants
- Data exports available via EXPORTER
- Free service

PROs

ReCoord

- Monthly updates assured accuracy and completeness by HCE RCT
- Unique data captures
 - characteristics specifically important to DOD (TRL, RDT&E program element category) for progression of the translational pathway and portfolio analysis
 - characteristics specific to audiological/vestibular research for trends in evolution of new medical concepts
 - timelines for events along the project progression to identify/address bottlenecks and track progress
 - Non-federally funded research (GME research, sponsored projects)
- Reporting capabilities across full database
- Utilizes Access system; user friendly, common competency, COTS product, DOD approved software
- HCE can use RePORTER's EXPORTER to download queries and upload into Access for cross-analysis.
- Can also roll in and capture DOD extramural investments not using RePORTER.

- Requires self-report from investigators
 - Guidelines for reporting not always followed
 - Expect entry gaps within and across projects
 - Timeliness of entry may vary
- Does not yet capture DOD; will not capture ~~not~~ audiology-specific elements
- No analytical tools included/available
- Not all federal agencies use this
 - Timeline for DOD coming online is unknown; likely will not be comprehensive of all DOD RDT&E funding lines across services
 - Does not capture VA funding data
- No record of non-funded submissions, non-federally funded projects, project status, collaborating organizations or investigators, knowledge product outcomes beyond PubMed

CONS

- Requires MOAs with collection sites within the CAVRN, and thus a phased implementation approach over a 3 year period. Only the first 6 sites (highest output of DOD intramural research) are online and have populated the database.
- Human resources ((1) 0.05 FTE HCE DBA and (7) 0.05 RCT members) are required
- DOD research execution only, at this time. Roll in of VA portfolio data is pending MOA.