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

3 NOV 2016

MEMORANDUM FOR SGVOU
ATTN: EARL GRANT JR

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **What is Research?** presented at/published to **Resident Research Fundamentals Course (Gateway Club), JBSA-Lackland, TX 27 Oct 2016** in accordance with MDWI 41-108, has been approved and assigned local file #**16383.**

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

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) (SG5 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.

7. Submit your completed form and all supporting documentation to the CRD 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 (DITC). See 59 MDWI 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 DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"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."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Earl Grant, Jr., GS-14, 59 MDW/ST/SGVOU	☐ YES ☒ NO	

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:
What is Research?

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 meting.)

☒ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)
Resident Research Fundamentals Course (Gateway Club), JBSA-Lackland Tx, 27 Oct 16

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	
N/A	

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	14. DUTY PHONE/PAGER NUMBER
Lopez, Raquel, L., raquel.lopez.2.ctr@us.af.mil	210-292-3366

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 Earl Grant Jr.	GS-14	59 MDW/ST/SGVOU	
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 MDWI 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	17. AUTHOR'S SIGNATURE	18. DATE
Earl Grant, Jr.	Earl Grant Jr	
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**20. APPROVING AUTHORITY'S SIGNATURE**	**21. DATE**
KEVIN STEEL, LTCOL, 59MDW/ST		

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 11/1/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16383
24. DATE REVIEWED 1 Nov 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

Presentation for resident research day 27 Oct 2016

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	29. REVIEWER SIGNATURE	30. DATE
1 Nov 2016	KUPFERER.KEVIN.R.1086667270 Digitally signed by KUPFERER.KEVIN.R.1086667270 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=KUPFERER.KEVIN.R.1086667270 Date: 2016.11.01 14:11:29 -05'00'	1 Nov 2016

2nd ENDORSEMENT (502 ISG/JAC Use Only)

31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA

33. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	35. REVIEWER SIGNATURE	36. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

37. DATE RECEIVED	38. DATE FORWARDED TO 59 MDW/SGVU
November 2, 2016	November 2, 2016

39. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	41. REVIEWER SIGNATURE	42. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	IINUMA.KEVIN.MITSUGU.12962 27613 Digitally signed by IINUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=IINUMA.KEVIN.MITSUGU.1296227613 Date: 2016.11.02 14:22:13 -05'00'	November 2, 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

59th Medical Wing

What is Research?

Earl Grant Jr., PhD
Director, Quality Assurance & Education
59th Clinical Research Division

Why are we here?

Warrior Medics – Mission Ready – Patient Focused

BLUF:

- DoD is a high reliable organization focused on safety
- Regardless of the type of activity being conducted, our primary goal should always be to protect any humans involved

Objectives:

- Distinguish the difference in non-research and research
- Identify key research "triggers"
- Know where to go to have your questions answered

*Key Reference: DoDI 3216.02_ AFI 40-402 *Protection of Human Subjects*

Non-Research vs Research

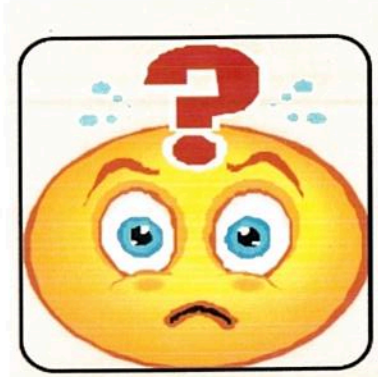
Warrior Medics – Mission Ready – Patient Focused

	Research (Utilizing)	EBP (Implementing)	QI (Conducting)
The question	*"**What** is the best thing to do"?*	*"**Are we** doing the best thing"?*	*"Are we doing the best thing... **right, and continuously**?*
Process	• Search the literature to determine the gap • Ask a research question or • Test a hypothesis • Generate new knowledge • Disseminate findings	• Search/appraise internal and external evidence • Implement practice change based on best evidence • Measure outcomes of practice change • Disseminate findings	• Monitor evidence-based practice change and outcomes continuously • Modify practice based on results • Generate internal evidence • Improve care
Purpose	Research is focused on... ***discovering new knowledge*** **that can be generalized to large groups of people.**	EBP is focused on... ***implementing knowledge*** **through practice change in a narrow population and measuring outcomes.**	QI is focused on ... ***generating internal evidence*** **about process and outcomes in the setting/environment that generated it.**
Techniques and Models used	Quantitative Research Methodologies Qualitative Research Methodologies	PICOT, ARCC, PARIHS, Stetler, Rosswurm & Larrabee, Iowa, Hopkins	PDCA, DMAIC, Six Sigma, TQM, Lean process, dashboards and scorecards
IRB	**Yes** (for protection of human subjects)	**Yes** (for protection of data and publication)	**Yes** (for publication)

Research is :	EBP questions are:	QI/PI process is:
• Directional • Based on theory • Generalizable • High reliability	• Not directional • Based on clinical inquiry • Outcomes focus • Not generalizable • Varied reliability	• About fixing problems • Based on internal data • Process focus • Not generalizable • Limited reliability
"What is the best thing to do"?	***"Are we doing the best thing"?***	***"Are we doing the best thing right and continuously"?***

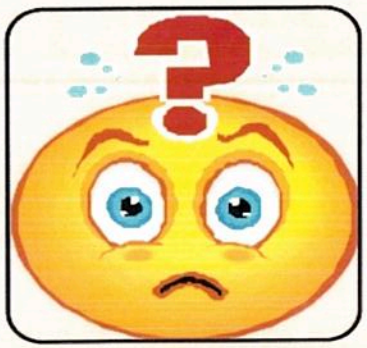
Non-Research vs Research: It's all about the question?

Warrior Medics – Mission Ready – Patient Focused



No Answer to the Clinical Question

- **Research Project**

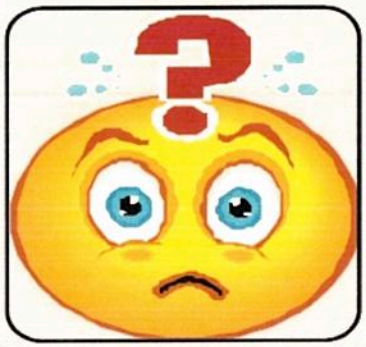


Answer to the Clinical Question

- Not Done in Hospital
- **EBP Project**

Answer to the Clinical Question

- Hospital Policy
- Not Doing It
- **QI Project**



Answer to the Clinical Question

- Hospital Policy
- Doing It
- Not on the pm shift
- **Education Project**

"Research"

Regulatory Definition: 32 CFR 219.102(d)

Research means a systematic investigation, including research development, testing and evaluation (RDT&E), designed to develop or contribute to generalizable knowledge.

- Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

"Research" Dissected

Systematic Investigation:

- In order for an activity to meet the definition of research, it must first be a "systematic investigation"
- For an activity to constitute a "systematic investigation," it must:
  - Test an hypothesis
  - Be organized into a process or procedures
  - Collect and/or analyze information.
- Short-hand: "data-based hypothesis testing"

"Research" Dissected

Generalizable Knowledge:

- Generalizable knowledge is knowledge or information or outcomes of the activity that can be applied beyond the context of the original activity

- Generalizable knowledge is intended to expand understanding of a condition or population, or add to the body of knowledge in/about a particular field (e.g., Phase III clinical trials)

"Research" Dissected

Generalizable Knowledge:

Activities that are intended solely to improve the care or experiences of an individual or of members of the target group do **NOT** result in generalizable knowledge

Examples:

- *Individual-specific activities*: Medical treatment, Educational or Professional mentoring, etc.
- *Population- or Program-specific activities*: Quality Assessment (QA), Quality Improvement (QI), Program evaluation

"Research" Dissected

Designed:

- No investigation, systematic or otherwise, has a certain outcome
- Reason for the activity must be identified by the investigator (or individual proposing the activity)
  - If the intent of the activity is unclear – **ASK! Don't guess!**
  - Look beyond the abstract or "purpose" statement.
- To meet the definition of research, intent of activity must be "to develop or contribute to generalizable knowledge" – but the investigator doesn't need to use that phrase
- Note: Intent to publish is not equivalent to "designed to be generalizable" – journals may publish reports of QA/QI/program evals

"Research" Dissected

Develop or Contribute:

- To meet the definition of research, the activity must be designed to create or advance generalizable knowledge in some way

- The outcome of the activity need not be actually generalizable in order for the activity to meet the definition of research

  Example: Pilot studies usually have sample sizes that are too small for results to be broadly generalizable, but they meet the "develop or contribute to" criteria and, thus, the def. of research

- Activities that may contribute to generalizable knowledge, but are not intended to do so, are not research ("…designed…")

  Example: Creation of medical or student records

"Human Subjects"

Regulatory Definition: 32 CFR 219.102(f)

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual; or
2. Identifiable private information.

An *Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An *Interaction* includes communication or interpersonal contact between investigator and subject.

Private Information

- *Private information* includes info about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and info which the individual can reasonably expect will not be made public (e.g., medical record).

- Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research Determination Flowchart (59 MDW)

Warrior Medics – Mission Ready – Patient Focused

Is my activity "Research"?

Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge?	
☐ No	→ The activity is not research, go to **Item 4**
☐ Yes	→ **STOP** The activity is "research" and must be submitted to the IRB.

Am I conducting "Research Involving Human Subjects"?

Q1. Does the research involve obtaining information about living individuals?		
☐ No	→ **STOP** The research **DOES NOT** involve human subjects; submit to the IRB for official research determination.	
☐ Yes	→ **Q2.** Does the research involve collecting data through intervention or interaction with the individuals?	
	☐ No	→ **Q3.** Is the information to be obtained individually identifiable *(i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)*?
		☐ No → **STOP** The research **DOES NOT** involve human subjects; submit to the IRB for official research determination.
		☐ Yes → **STOP** The research **DOES** involve human subjects and must be submitted to the IRB.
	☐ Yes	→ **STOP** The research **DOES** involve human subjects and must be submitted to the IRB.

Take-Away Points

Regardless of the activity the primary goal should always be to protect our beneficiaries and/or staff.

- Research applies a methodology (quantitative or qualitative) to develop new knowledge.
- EBP seeks and applies the best clinical evidence toward making patient-care decisions.
- QI uses systematic processes to improve patient outcomes.
  - Some QI activities may be designed to accomplish a research purpose, as well as the purpose of improving the quality of care. Federal regulations and IRB approval may apply.

If In Doubt…Ask For Help

Warrior Medics – Mission Ready – Patient Focused

59 MDW Clinical Research Division (CRD) IRB Protocol Office:

- *210-292-7141*
- *59CRD.protocol@us.af.mil*

59 MDW Science and Technology Office:

- *210-292-2097*
- *59mdw.st@us.af.mil*

BAMC/SAMMC Department of Clinical Investigations

- *Department Administration (210) 916-9027/4405/4495*

Questions?

Warrior Medics – Mission Ready – Patient Focused