

EBP, EDO, and EIRB within DHA

Administrative Processes and Infrastructure
Standardization

TSNRP

Fostering Excellence in Military Nursing

Disclaimers

The views expressed during this discussion are those of the panelists and do not necessarily reflect the official policy or position of the Department of the Navy, Department of the Army, Department of the Air Force, Defense Health Agency, Uniformed Services University, Department of Defense, nor the U.S. Government.

Panel Member

- Laurie Migliore, Lt Col, USAF, NC, PhD
 - 59th Medical Wing, Science & Technology, Center for Clinical Inquiry, JBSA, TX
- Jeff Ransom, MAJ, USA, PHD, DNP, FNP-BC
 - Madigan Army Medical Center, JBLM, WA-Center for Nursing Science & Clinical Inquiry (CNSCI)
- Rachel Newnam, CDR, NC, USN, DNP, FNP-BC
 - Phase II Site Director, FNP/WHNP Program, Uniformed Services University, Bremerton, WA

Questions for Discussion

Pre-registration questions:

- Have you submitted an EBP/QI/PI to an eIRB?
- Does your facility have a standardized EBP checklist/review tool?

Afternoon focus group discussion:
















- Develop a visual display illustrating process/resource consistencies across DHA sites
- Discuss gaps, opportunities for collaboration, potential for streamlining processes to ensure rigorous/robust nurse-driven EBP initiatives across DHA



Current State




EBP Approvals, Forms, Support

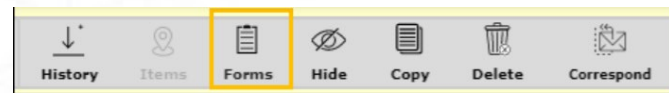
Current Process: EBP Approvals, Forms, Support

Military Branch	Formal Submission via eIRB	Submitted Under PI/QI/EBP Umbrella	Exemption Determination Official (EDO) Review	Formal Determination Letter/Number Received	Paired with EBP Mentor Throughout Process
USAF					
USN					
USA					













 Yes
  Sometimes Some sites
  No

Formal Submission through eIRB

Military Branch	Formal submission to EIRB
USAF	
USN	
USA	



When you click on the "Forms" icon, a list of all submission forms will show in a pop-up window.

Submission Form List			
Regulatory Forms			
IRB Forms	Version List	Start a new Submission	Edit Incomplete Submissions
EIRB Publication Clearance Cover Sheet			
EIRB Reportable Event Form			
EIRB Modification Form			
EIRB Continuing Review (Lead and Single Site Only)			
EIRB Periodic Administrative Report			
EIRB Closure Form			

6/29/2020

IRIS: Protocol Application

EIRB Protocol Template (Version 1.0)

1.0 General Information

***Please enter the full title of your study:**

COVID-19 Biobehavioral-Focused Palliative Care Toolkit

***Please enter the Protocol Number you would like to use to reference the protocol:**

abcde
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

Yes No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?

Department Name

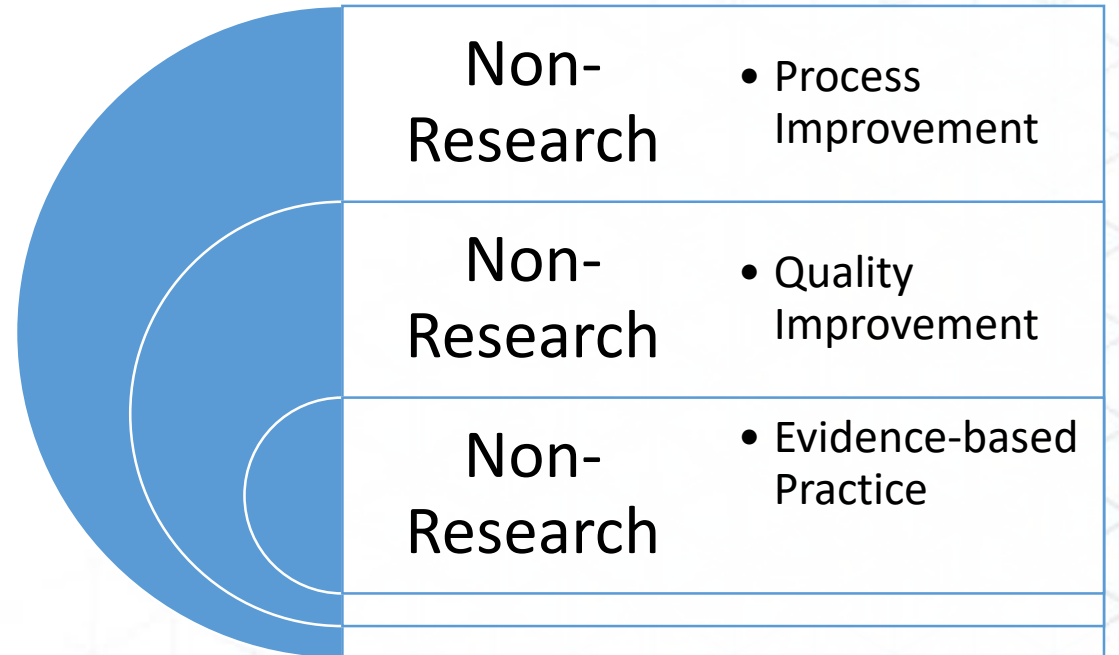
USAF - 59th Medical Wing (59 MDW)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

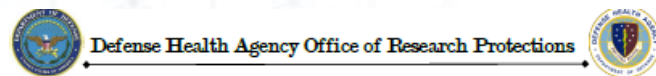
Submitted Under PI/QI/EBP Umbrella

Military Branch	Submitted under PI/QI/EBP umbrella
USAF	●
USN	●
USA	●



Exemption Determination Official (EDO) Review

Military Branch	Exemption Designated Official (EDO) Review
USAF	
USN	
USA	



DHA Office of Research Protections Checklist Exemption Determinations Checklist # CL-03-003; Version 2.10

The purpose of this review is to ensure that exempt research meets DoD, DHA, and institutional requirements. This checklist can be used to conduct research, human subjects research and exemption determinations.

Guidance, instructions, training, and important points of contacts can be found on the DHA ORP milSuite page: <https://www.milsuite.mil/book/groups/office-of-research-protections-orp-dha>.

Section 1: Submission information

Date Received: Click here		
Local/IRB #:	EIRB Ref #:	DHA # (COHRP Use Only):
PI:	PI Email:	PI Phone:
Gov. Proj. Manager:	GPM Email:	GPM Phone:
Study Title:		
Lead Site:	DHA Site:	
Populations (be sure to consult 32 CFR 219, 45 CFR 46 Subparts B-D, DoDI 3216.02 and other relevant regulations to ensure that the requirements for the applicable population have been addressed):		
<input type="checkbox"/> Normal, Healthy Adults	<input type="checkbox"/> Children	<input type="checkbox"/> Decisionally Impaired
<input type="checkbox"/> Employees	<input type="checkbox"/> Military	<input type="checkbox"/> Pregnant women/fetuses
<input type="checkbox"/> Prisoners	<input type="checkbox"/> DoD Civilian	<input type="checkbox"/> Non English Speaking
<input type="checkbox"/> Patient population	<input type="checkbox"/> Students	<input type="checkbox"/> Other:
List any supporting documents:		

Section 2: Who is conducting the activity? (Instructions: Question 1 must be "yes"; if question 1 is "no" either question 2 or question 3 must be "yes" and the reviewer should STOP and use the HI checklist)

Element/Requirement	Met?		Comments
	Yes	No	
1. Is the DHA institution conducting the activity?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is the DHA institution supporting the activity with funds or assistance that is provided to a non-DoD institution through a grant, contract, or similar arrangement subject to the DFARS or other applicable DoD regulations, such as the DoD Grant and Agreement Regulations? <i>DoDI 3216.02 Definitions</i>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is the DHA institution assisting with the activity by providing facilities, equipment, personnel, access to or information about DoD-affiliated personnel for recruitment, or data or specimens to a non-DoD institution? <i>DoDI 3216.02 Definitions</i>	<input type="checkbox"/>	<input type="checkbox"/>	

Highest Possible Sensitivity of Information is CONTROLLED
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EDO Training - March 21-22, 2022

created by YOSHANI RYAN on Aug 30, 2021 2:47 PM, modified on Aug 30, 2021 2:47 PM

DESCRIPTION

DHA ORP will be offering Exemption Determination Official (EDO) training on a quarterly basis. This training is suitable for both new EDOs and current EDOs who need to renew their training (reminder: EDOs need to re-train every 3 years to continue making determinations).

es are currently scheduled for **Monday and Tuesday, 1200-1400 EST/EDT**. Please let us know if you are interested in the training but the days/times pose an inherent conflict.

For each course, if you cannot attend one of these EDO training courses we will need at least 3 people to be enrolled at least 2 weeks (10 business days) before the course is scheduled to begin. **We require a minimum enrollment of 3 people to meet the minimum enrollment threshold.** To register, please send an email to edo@mil.mil with your name, institution, whether the course will be new or refresher course, and the date of the course you would like to attend. Enrolled participants will receive an invitation once the enrollment threshold is reached.

EDO Training Schedule:

20-21 September 2021

6-7 December 2021

21-22 March 2022




13-14 June 2022

19-20 September 2022

5-6 December 2022



Formal Determination Letter

Military Branch	Formal determination letter/number received
USAF	
USN	
USA	



DEPARTMENT OF THE AIR FORCE
60TH MEDICAL GROUP (AMC)

MEMORANDUM FOR 60MDG/SGSE

FROM: 60 MDG/SGSE

SUBJECT: Exempt Research Determination and Approval Notice

1. A Proposal for an Exempt research study **FDG20180009E** entitled, "**Identifying the Core Content of Military Identity for Psychological Understanding**" was submitted to the Clinical Investigation Facility (CIF). The Principal Investigator of this proposed research is **Lt Col Laurie Migliore**.
2. As a designated Exempt Determination Official (EDO), under authority granted by the DGMC Institutional Official, I have determined that this human subject research is eligible for exemption under **Category 2 [32 CFR 219.101(b) (2)]** in that the research procedures **ONLY** involve educational tests, survey or interview procedures, or observation of public behavior. This data is non-identifiable either directly, indirectly, or by a coding procedure linked to the subject's identity. Disclosure poses no risk of criminal or civil liability, or will not be damaging to subjects' financial standing, employability or reputation.
3. As a result of this determination, your proposal was approved on **9 July 2018**, and is **EXEMPT** from Institutional Review Board (IRB) oversight. The IRB will be notified of this determination. However, please note that any changes to this study may affect the exempt status of your research and must be reviewed by an EDO. IAW AFI 40-402, all investigators engaged in human subject research, whether exempt or not, must have a current human protections training certificate on file with the CIF. The investigator must provide an annual update to the CIF on all research activities associated with this study.
4. If you have any concerns, please contact the CIF Protocol Office at 423-7400. Good luck on your new research endeavor!

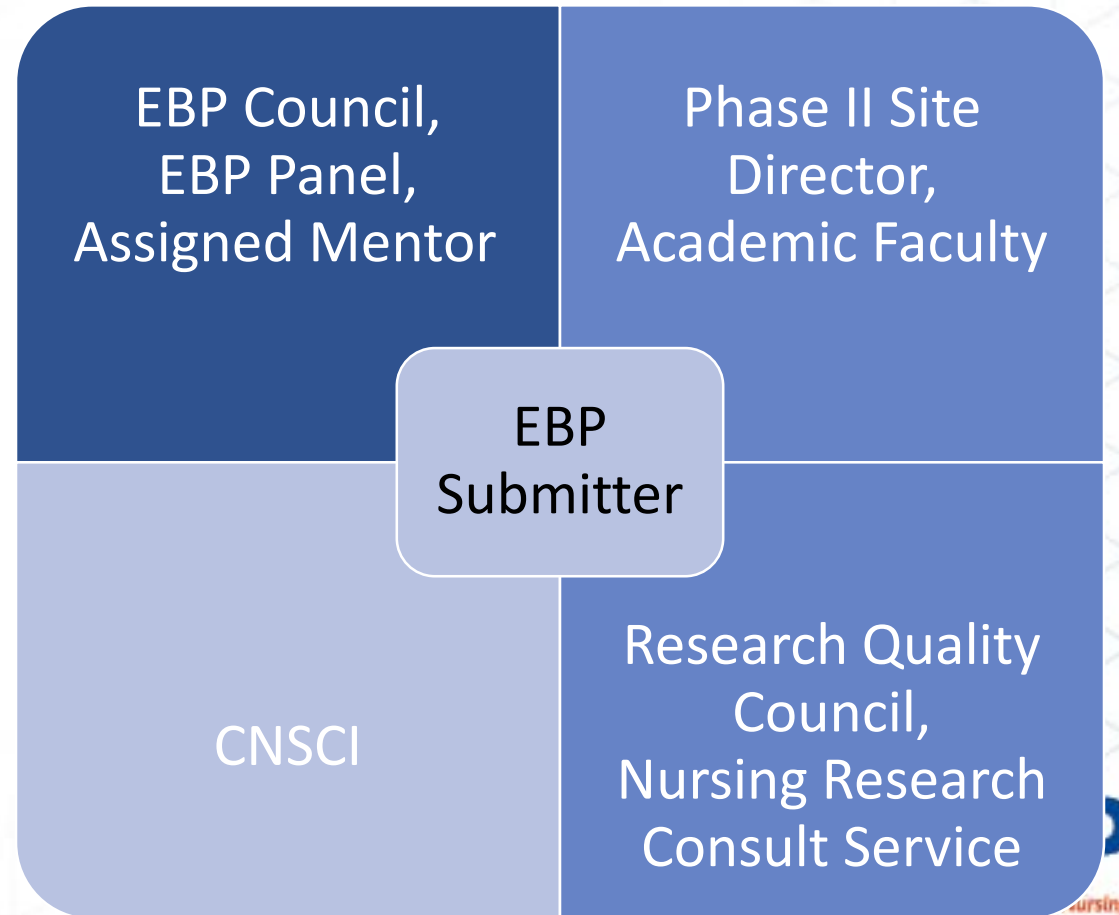


IAN J STEWART, Lt. Col, USAF, MC
Exempt Determination Official

TSNRP
Fostering Excellence in Military Nursing

Paired with a Mentor

Military Branch	Paired with EBP mentor throughout process
USAF	●
USN	●
USA	●



Challenges

- IRB Regional consolidation
- eIRB structure
- DHA transition
- Nursing-specific language and worldview
- Administrative burden for reviewers
- Leveraging EBP SMEs at sites without research and EBP cells

Opportunities

- Establish a forum for EBP initiative reviews (panel, committee, council)
 - Charter specifying objectives and ROEs
 - Appointed members (multidiscipline?)
 - Clear roles/responsibilities for members
 - Standardized language
 - Utilizes standard EBP review/submission checklist
- Establish standard products
 - EBP proposal template
 - EBP review checklist
 - Common language tool
 - Mentor qualifications and toolbox
- Establish Joint communication platform for crosstalk (website, meetings, etc.)
- Identify current EBP best practices across services to synergize efforts



Future State

Standardization in Submissions, Support, and Resources for EBP Initiatives

Suggested Recommendations

- Establish a TriService EBP/Clinical Inquiry Working Group to address challenges & opportunities
- Identify EBP “champions” for each component and at each DHA market and MTF
- Establish a formal strategic plan with SMART goals, timelines, milestones
- Consider a grant submission to fund the above work