

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



11 APR 2017

MEMORANDUM FOR ST

#### ATTN: COL BRENDA MORGAN

#### FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled <u>What is the Process? Approvals for Survey Research in the</u> <u>Department of Defense (DoD)</u> presented at/published to <u>TSNRP Research/EBP</u> <u>Dissemination Course, Ellicott City, MD, 26 April 2017</u> in accordance with MDWI 41-108, has been approved and assigned local file #17175.
- 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.

da Steel-Goodwin

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

Warrior Medics — Mission Ready — Patient Focused

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS INSTRUCTIONS USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING 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 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 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). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 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. 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the

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

"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."

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## What is the process? Approval of Survey Research in the Department of Defense (DoD)



Nursing Survey Working Group of the TSNRP Biobehavioral Health Research Interest Group

CDR Virginia Schmied Blackman, PhD, CCNS LTC Kristal Melvin, PhD, NP-C Col Brenda Morgan, PhD Ms. Megan Foradori, MSN 26 April 2017

### Disclaimer

The views, opinions, and/or findings reported in this presentation are those of the authors and should not be construed as the official policy or position of the Department of Defense or the U.S. Government.

Presenters have no conflicts to disclose.

DoD 8910.01 Glossary and Terms

Information: Any communication or representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numeric, graphic, cartographic, narrative, or audiovisual forms.

**Collection of information:** Obtaining or causing to be obtained, soliciting, or requiring of facts or opinions regardless of form or format used.

Survey: Systematic data collections, using personal or telephonic interviews, or selfadministered questionnaires, in paper or digital format, from a sample/census of  $\geq 10$ persons as individuals/representatives of agencies that elicit attitudes, opinions, behavior, and related demographic, social, and economic data to identical questions that are to be used for statistical compilations for research or policy assessment purposes.

RCS: Report Control Symbol

**OPA: Office of People Analytics** (Formally Defense Data Manpower Center/DMDC)

RSSC: Research, Surveys, and Statistics Center (RSSC)/Retention and Readiness

WHS: Washington Headquarters Service



Describe the background and issues regarding DoD level research and evidence-based practice (EBP) survey approval processes resulting in a nursing TriService working group.

Contrast current Service-specific survey approval processes for Army, Air Force, and Navy.

Identify Service-specific and DoD survey approval subject matter experts and mentors.

## Background/Problem

Researchers report spending up to a year maneuvering through the process of obtaining DoD level approval to conduct cross-component surveys.

Single-Service or Service-specific approval processes are reported to be confusing.

The survey approval process between services is inconsistent and time consuming.

Barriers, real or perceived, lead to researcher hesitation to use survey methods, or restrict their survey research to a single service, in order to expedite the process, when a multi-component survey would provide better insight.

#### **Results:**

Lack of joint research efforts; Redundancy in research efforts; Increased use of resources (i.e. money, time).

Nursing Working Group met to assess/clarify Service-specific and cross-component survey approval processes.

### Working Group

- The working group formed as part of the Behavioral Health Research Interest Group (BHRIG) facilitated by Megan Foradori, began meeting December 2016
- Working group members included Army, Air Force, and Navy nurse scientists
- Working Group goals:
  - review service-specific and DoD policies related to approval process for conducting surveys
  - develop presentation and handout on the current process to increase awareness among nurses

### Working Group Accomplishments

To date:

- Reviewed/mapped the current survey approval process for each service
- Contacted DoD POCs for information about current DoD approval process
- Developed recommendations for nurses (tips for conducting surveys)
- Developed training module outlining the processes along with a quick reference guide that includes SME/process POCs and nurse scientist mentors





#### Example 1:

Research study using anonymous surveys to collect data on nurse compassion fatigue in a trauma unit

#### Questions to answer:

Who are the nurses?
Civilian, contractors or military?
Army only or multi-component?
Leader sponsorship?
Deputy or Commander -- Colonel (0-6) or higher
IRB determination?
Human Subjects?
Exempt or expedited?
How many surveys?
>100 → ARI review

 $\circ$  If yes  $\rightarrow$  ARI review

If contractors → IMCO review also required

#### Example 2:

EBP project regarding nurse and patient satisfaction with a new (EVIDENCE-BASED) discharge process

#### Questions to answer:

Who are the nurses? • Civilian, contractors or military? • Army only or multi-component? Leader sponsorship? • Deputy or Commander -- Colonel (0-6) or higher **IRB** determination? • Human Subjects? Exempt or expedited? How many surveys?  $\sim$  >100  $\rightarrow$  ARI review Sensitive topic?  $\circ$  If yes  $\rightarrow$  ARI review

If contractors  $\rightarrow$  IMCO review also required

#### Army Tips To Remember: #1 Army sponsor (of the survey project)

- Sponsor agrees "Mission critical" and agrees to take action on findings
- Usually an O-6 (COL) is sufficient
- Student led projects and those "external" to the Army
  - Brigadier General (BG) or higher military or GS civilian required
  - BG must:
    - Provide oversight
    - Monitor progress
    - Approve any release of findings
    - Shares responsibility for negative publicity

bm5 1. Is a student project for an AD student at USU considered "external?" What about an AD Army student on LTHET at a civilian institution? Will it be the the O-7 who "owns" the student, or the O-7 who owns the people whom the student wants to survey? brenda morgan, 3/29/2017



#### Air Force-Specific Survey Requirements

All Surveys conducted as part of Human Subjects Research are reviewed by the Institution Review Board (IRB).

Review of ALL attitude and opinion non-human subject research surveys must be coordinated with the AF Survey Office.

- The purpose of the AF Survey Office
  - Control, conduct and approve attitude and opinion surveys, research and program evaluations at the Air Force level
  - Provide oversight to ensure surveys meet mission requirements, provide optimal results and fulfill the informational needs of AF Senior Leaders and Functional Authorities
- Assign Survey Control Number (SCN) to approved surveys (also SCN-NR)
- Maintain website for all AF approved surveys (AF Portal)
- Refer to handout for website/contact information

### Air Force-Specific Survey Office Coordination/Requirements

Administrative review of survey questions and content (DoDI 8910\_01; AFI 38-501).

- Request Survey Control Number (SCN) via AF Form 4453 (DoDI 8910\_01; AFI 38-501).
- Sponsorship support must be AF HAF/SAF 3-letter; or highest Functional Authority--Person with authority to act on the findings (AFI 38-501).
- Action Officer (A/O) must be a government representative (AFI 38-501)

 Review by a Survey Office Behavioral Scientist if the survey office is conducting the survey; research review conducted IAW Human Research Protection Program guidance (32 CFR 219; AFI 40-402).

#### Air Force Tips to Remember

- Student research requests are denied, regardless of who is funding (i.e. AFIT) https://www.my.af.mil/gcss-af/USAF/ep/browse.do?programId=t330D98A149CA5AFC0149CF35B7290107&channelPageId=sE3494DD04562FCC901456BE0545C017A#a8
- Review of clinical surveys are not required
- Per DODM 8910.01, I.b.(14); DODM 8910.01, 8.B (5): all clinical research is exempt from needing a
- Surveying bargaining unit civilians coordinate with Civilian Personnel Labor Relations
- Privacy: Freedom of Information Act (FOIA); Privacy Act 1974; Operations Security (OPSEC); if open ended questions include mandatory

Disclaimer

- Non dot-mil website utilization PA has oversite of publically releasable information
- Multi-branch services (e.g., Air Force, Army, Navy) DoD level
  - AF rep on Inter-Service Survey Coordinating Committee (ISSCC) (DoDI 1100.13)



### Navy Survey Approval Process

Navy survey approval process conducted in accordance with OPNAV 5300.8C *Objectives*:

Ensure surveys provide maximum benefits to Navy leadership and the Fleet:

- At lowest possible personnel cost
- With least disruption to operational tempo

Provide technical review of Fleet surveys by survey experts

Reduce survey burden on the Fleet

Avoid over-surveying and survey duplication

# Major Functions of Navy Survey Approval Manager

Provides technical review, approves proposed surveys in accordance with OPNAV 5300.8C

Maintains Navy Survey Policy Website <a href="http://www.public.navy.mil/bupers-npc/organization/NPC/SurveyPolicy/Pages/default.aspx/">http://www.public.navy.mil/bupers-npc/organization/NPC/SurveyPolicy/Pages/default.aspx/</a>

Determines need for Protection of Human Subjects approval, per SECNAVINST 3900-39D Determines if survey plans meet website security requirements of SECNAVINST 5720.47B Requests and issues OPNAV Report Control Symbols (RCS) that "license" Navy surveys

## Major Functions of Navy Survey Approval Manager

Alerts POCs of "unlicensed" surveys of submission requirements

Facilitates the survey application process through direct contact with individuals

Provides consultation on technical survey issues for N1 and other Navy survey sponsors/customers

Participates as Navy Survey Representative to the Inter-Service Survey Coordinating Committee (ISSCC) chaired by DMDC



### **Navy Survey Submission Requirements**

- 1. Survey request letter, to include:
  - Purpose of survey
  - Justification for doing a survey as opposed to another method
  - Participants, including numbers and key groups of interest
  - How the survey was developed
  - Communications plan for results
  - Sponsor POC
  - Performing activity POC
- 2. Flag/SES (or appropriate designee) endorsement letter, indicating total number of man-hours and approximate cost of those man-hours
- 3. OPNAV 5214/10 Report Analysis Data Form, which estimates costs based upon most recent pay tables
- Final survey draft

Privacy Statement including notice of voluntary participation must be displayed at beginning of survey





## **DoD Information Collection Policies**

DoD Instruction 1100.13 "DoD Surveys"

• Establishes policies, assigns responsibilities, and provides procedures for information *collection involving use of surveys*. Implements policy/guidance in 8910.01...for survey requests coordination, mandatory review, and standard used in reviews, as well as development of effective surveys.

DoD Instruction 8910.01, "Information Collection and Reporting"

• Establishes policies and assigns responsibilities for the collection of information and the control of the paperwork burden (Ch 35 of Title 44, U.S.C.)

DoD Manual 8910.01, Volumes 1 (Internal) and 2 (Public), "Procedures for DoD Information Collections"

DoD Information Collections Website: http://www.dtic.mil/whs/directives/collections/index.html

Not everyone knows about the survey approval regulations - or follows them!

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Per DoDI 1100.13, DoD Surveys

a. A survey requesting participation of personnel from more than one DoD Component or a DoD Component-sponsored survey of members of the public will be reviewed by USD(P&R), through the Director, DMDC, to ensure that

(1) The survey minimizes exposure of DoD personnel, Service members families, and members of the public to unwarranted information collection (e.g., survey solicitations).

(2) The survey is best means to produce the most valid information with least burden.

(3) Adequate safeguards in place to ensure the consent of the individual before any personal information (written or oral) is solicited or collected (DoDD 5400.11).

(4) Procedures in place to protect the identification of respondent's data from disclosure.

(5) Survey meets the standards required by the DMDC or Office of Management and Budget (OMB), according to the guidelines in the DMDC or OMB Survey Supporting Statements. https://www.dmdc.osd.mil/dmdcrs/

Per DoDI 1100.13, DoD Surveys (continued)

b. The requesting DoD Component must contact their information management control officer (IMCO), who will help coordinate development, submission, review, and approval of all survey documents and ensure that:

(1) The available information, including results of *past or current surveys* of the same or similar individuals, is not adequate to fill the need.

(2) Current approved and licensed surveys cannot provide the required information.

c. The requesting DoD Component must request a review of the survey in the DMDC DRS at https://www.dmdc.osd.mil/dmdcrs/.

d. When contacted by DMDC, the requesting DoD Component submits the collection instrument, supporting materials (e.g., copies of survey letters or emails), the DMDC and/or OMB survey supporting statements, and the DD Form 2936, "Request for Approval of DoD Internal Information Collections" (as applicable).

Per DoDI 1100.13, DoD Surveys (continued)

e. Upon receipt of all required documentation, DMDC will conduct its initial review of the survey within 15 working days and assist the requesting DoD Component, as necessary.

(1) Additional reviews may be necessary depending on the complexity of the survey's subject, methodology, or statistical design.

(2) If DMDC determines the data collection does not meet the definition of a survey they will indicate their exempt determination.

(3) A DMDC exempt determination does not exempt the requesting DoD Component from obtaining a valid report control symbol (RCS) or OMB control number as required.

f. Upon review, DMDC forwards a memorandum recommending approval of the survey, and all supporting materials, to the requesting DoD Component who then send to WHS for issuance of a valid RCS or submission to OMB for an OMB control number.

Per DoDI 1100.13, DoD Surveys (continued)

g. If DMDC recommends disapproval, they forward a non-concur memorandum to the requesting DoD Component documenting the reason for the decision. Resolving the recommended disapproval may consist of:

(1) Phone, e-mail, or memorandum communication that involve ISSCC members, Component's IMCO, or other Component senior leadership.

(2) A DMDC memorandum to the USD(P&R) requesting a final decision on the recommendation to disapprove.

- Without USD(P&R) recommended approval, the survey will not be approved by WHS for an RCS license or submitted to OMB for an OMB control number.

h. All surveys covered by this instruction must display at least one clearance number, such as an RCS license or OMB control number.

i. DMDC review of a survey is not a substitute for review by a human subjects' protection program AND survey review by a human subjects' protection program officer is not a substitute for DMDC review.

Per DoDI 1103.13

Cross-component surveys (e.g., Navy and Air Force) must be reviewed by Defense Research, Surveys, and Statistics Center (RSSC)/Retention and Readiness Office of People Analytics (**OPA**)(previously DMDC) and approved/licensed by Washington Headquarters Services (**WHS**)

#### OPA survey review <u>does not</u> equal survey approval

- Needs additional coordination with Privacy, HRPP, CIO, Records Management, etc.
- Approval is by WHS for Internal Collections and by OMB via WHS for Public Collections
  - Public Collections include DoD Contractors; so surveying ALL nurses across MTFs requires OMB approval.

Single component surveys (e.g., Army) approved by the Service-specific survey organization

Survey Example: Variation in provider practice for pain management after a given procedure; Participant reported outcomes using validated instruments like the McGill Pain Questionnaire, Health-Related Quality of Life instrument, or Beck Depression Inventory IF the research participant is NOT the patient (for example, caregiver studies).

Not everyone knows about the survey approval regulations - or follows them!

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#### DoD Information Collection Process

DoD-level crosscomponent survey review/approval is done by the Office of People Analytics (OPA) (formerly DMDC) to ensure collections are valid, accurate, costeffective, mission essential and not duplicative.

Types of Information collection: *Public* and *Internal* 

#### **Cross-Component Surveys**



#### Who is considered a DoD Internal population?

There are two groups that make up a DoD Internal Population:

Active Duty Service / Military Members

Government / Federal Employees

Exception: 10 U.S.C. Chapter 88, Sec. 1782 "Surveys of Military Families"

Must be used to determine the effectiveness of Federal programs relating to military families and the need for new programs.

- Members of the armed forces (active duty, active status, or retired);
- Family members of such members; and

• Survivors of deceased retired members and of members who died while on active duty. Responses must be voluntary.

Collection instrument must be a survey.

Example: POTFF Survey (Preservation of the Force & Family)

#### Timeline: about 3 months

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### **Public Information Collection**

 A survey of members of the general public (e.g., contractors) who aren't military or government employees.

#### Timeline

- OMB requires open comment periods, timeline can be lengthy. Requirements listed below require <u>4 MONTHS</u>:
  - 60 Day Comment Period beginning of process
  - 30 Day Comment Period end of process.
  - 30 Day OMB Review Period after 30 day comment period closes.
- Add in all the other offices involved with collection, increase to <u>6 MONTHS</u> on average. List of possible coordination offices:

PRIVACY - RECORDS and FORMS MANAGEMENT -DMDC - GENERAL COUNSEL - CIO -

#### MEMBERS OF THE PUBLIC

Individuals not employed by the Federal Government State, Tribal, or Local Governments Members of Industry Government Contractors Applicants for Employment Foreign Nationals Former/Retired Military/Veterans Spouses/Dependents Caregivers Private Sector doctors, nurses, attorneys Not for Profit Organizations

# **DoD Information Collection Approval Process**

Internal Information process for approval/license

#### **Process Participants**

Component Action Officer (AO)

### RCCS Process (per DoDI 8910.10)

Component Information Management Control Officer (IMCO)	Step 1: Contact the Component IMCO or the DoD ICO before drafting the DD Form 2936 action package.	Step 2: Complete a CAPE cost summary. The requesting Component's official signature on the DD Form 2936 is not required for those information collections prescribed in a	Component or OSD Privacy Official, the Component Records Manager, and the
Mandatory Coordinators		DoD issuance.	Component CIO as applicable.
Collection Respondents DoD Internal Information Collections Officer (DoD IICO)	Step 4: Routing the DD Form 2936 action package to respondents for coordination and approval is not required for those information collections prescribed in a DoD issuance.	Step 5: Submit the DD Form 2936 action package to the Component IMCO.	Step 6: The Component IMCO submits the DD Form 2936 action package to the DoD ICO.

## Why do I need a license?

•To reduce duplication and lower the cost of collections

•To ensure compliance with more than 300 laws, regulations, and issuances concerning:

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- Privacy and personally identifiable information
- Records management and disposition
- Information assurance
- Security
- Human research protection
- Survey construction best practices

# What doesn't need a license?

- 17 potential "exemptions" (list in Encl 3, Vol 1, DoDM 8910.01)
- Common examples include financial audits, substantive intelligence reporting, investigations of charges, and personnel records
- Exemptions for internal collections do not constitute exemptions from Congressional or public collection requirements (and vice versa)
- Exemptions for internal collections do not exempt the collection from the data protection laws, regulations, and policies (e.g., privacy, records, information assurance)

Ultimately the DoD ICO makes the final call/determination on exemptions...

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## Cross-Component Human Subject Research Surveys

WHS makes final determination. WHS, Director, and DoD human protection officials discussed and agreed that human subjects research that involved a survey would most likely be required to go through the survey review process and NOT be exempt.

Exemption in DoDM 8910.01 Vol 2 is really designed for *clinical research* rather than surveys of military members or other government employees.

Previously most have required survey review as an *internal collection* in addition to human subjects review.

Research surveys aren't usually treated differently than other personnel surveys but is up to WHS to determine.

The DoD survey program outlined in DoDI 1100.13 is a <u>separate</u> compliance process from the *information collections* program outlined in DoDI 8910.01.

- Survey approval (regardless of whether it is an information collection) contains different coordinations and requirements than information collection approval (regardless of whether or not it is a survey).
- If a project constitutes both a survey and an information collection, then it must undergo both approval processes (through DMDC/OPA for survey compliance, and through OIM for collections compliance).

# What about Human Subject Research Surveys?

Per DoDI 8910.01 Vol 2, 8. b.

Items not considered *public* information collections for purposes of the Paper Reduction Act (PRA) may include:

 Facts or opinions obtained from individuals under treatment or clinical examination in connection with research on, or prophylaxis to prevent, a clinical disorder; direct treatment of that disorder; or the interpretation of biological analyses of body fluids, tissues, or other specimens; or the identification or classification of such specimens. This includes medical records established as a result of this type of action.

• While this includes PATIENTS, it does not cover examinations of wellness or health-promoting behaviors, research conducted with family members, formal or informal caregivers of patients, or any persons AT RISK for a particular experience (i.e., persons who have deployed to a particular region, Service-members who have held a particular role)

\*Exemption does not cover the majority of research surveys conducted in nursing research

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bm4	Perhaps instead you could write: "While this includes PATIENTS, it does not cover examinations of wellness or health-promoting behaviors, resarch conducted with family members, formal or informal caregivers of patients, or any persons AT RISK for a particular experience (i.e., persons who have deployed to a particular region, Service-members who have held a particular role, etc.
bm6	are you saying wellness or health promoting behavios, research condcuted with family members or infomal caregivers, or any person at risk is considered part of public collections?
VB8	I don't know if it is PUBLIC or not, but from what I read in the DoDI, the types of research you described above are not within the narrow definition of "clinical research on, or prophylaxis to prevent a clinical disorder." VIRGINIA BLACKMAN, 3/31/2017

### Surveys as Instruments of Collection (Public)

- OMB'S CONCERN: THE PUBLIC IS OVERBURDENED BY SURVEYS
- DOD'S CONCERN: LOTS OF MONEY SPENT ON DUPLICATIVE WORK & LOW RESPONSE RATES

• <u>RESULT:</u>

- OMB reviews all surveys separately (Surveys cannot be combined with any other type of instrument).
- OMB requires a Supporting Statement for additional information.
- OMB requires that DoD conduct a statistical review of the package prior to review.
  - Mandatory DMDC review for all Surveys (or survey-like) collections.
  - Ensures best practices are being used in design and measurement.

### Surveys as Instruments of Collection

- Survey Monkey is <u>NOT</u> the best option.
  - Retains a copy of respondent information.
  - Has the option to SELL respondent information at their discretion.
- When is Survey Monkey okay?
  - Entered an agreement with Survey Monkey (beyond their standard subscriptions), and has cleared CIO for information security.
- DoD Guidance & Alternatives
  - DoD Guidance: DoD Instruction 8550.01: DoD Internet Services and Internet-Based Capabilities
  - ALWAYS Check with your CIO if there is any doubt.
  - ICE & MAX.GOV



### DoD Survey Approval Best Practice 1: Pre-coordinate

Before moving forward with efforts to do a survey or focus-groups, pre-coordinate with relevant DoD or Service survey review officials • Pre-coordination means contact them to discuss the idea in advance • Recently approved DoD Survey Burden Action Plan recommends precoordination to help reduce cost, burden, and duplication of DoD surveys and focus groups

Receiving a grant, or gaining IRB approval, or having a great idea, doesn't guarantee approval of any DoD survey, especially those on sensitive topics.

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## DoD Survey Approval Best Practice 2: High Level Sponsor

Seek a high-level (Flag/General Officer, SES) sponsor who will endorse the collection and will indicate an intention to use the results to meet a military program or policy requirement

Without a high-level sponsor who wants the study done, will take responsibility for it and will utilize the results, unlikely that the waiver will be granted or the survey/focus group will receive DoD or Service survey approvals

### DoD Survey Approval Best Practice 3: Allow Time for Approval

The approval process takes time - develop project timelines that allow for a lengthy approval process

IRB or Human Subjects Approval is just part of the process -

DoD (or Service) Survey Approval is a complex process that can be lengthy

 Usually need 3 months or more for entire process for Internal Collections

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 Public Collections (OMB approval) require 6 to 8 months or more

## Cross-Component Survey Approval Tip Sheet

### TIPS: Things to think about when developing your survey

- Does the survey
  - Have a 3-letter level Sponsor or appropriate level of Functional Authority?
  - Cross Functional Authority (FA) lines?
- Provide significant contribution to relevant Service/DoD policies and programs?
- Duplicate efforts of another survey?
- Does the survey require an IRB? (32 CFR 219 and AFI 40-402)
- Does the survey protect the respondent's confidentiality and anonymity? Is survey voluntary?
- Do the benefits to the Service/DoD outweigh potential costs (e.g., negative publicity, damage to morale or readiness, time burden on respondents)
- Is the survey's purpose to meet an academic requirement or a springboard for future research?
- Are the survey questions of appropriate length to avoid survey fatigue?
- Are survey questions essential to the goal of the survey?
- Are questions logical and sequential in placement on the survey?

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# Cross-Component Survey Approval SMEs/POCs

### Overall Working Group Summary: Implications for Military Nurses

DoD level survey coordination process can be confusing and intimidating.

Group recommendations include that nurses planning to conduct surveys:

- Start with valid, reliable survey instruments
- Be familiar with Service-specific & DoD policies covering survey approval

• Seek out SME/mentor early, to advise and facilitate the process Goal: After survey approval process training, there will be an increase in nursing research and EBP cross-component surveys.

### **Presentation Summary**

Describe the background and issues regarding DoD level research and evidence-based practice (EBP) survey approval processes resulting in a nursing TriService working group.

Contrast current Service-specific survey approval processes for Army, Air Force, and Navy.

Identify Service-specific and DoD survey approval subject matter experts and mentors.



### References

DoDI 1100.13, Surveys of DoD Personnel DoDI 8910\_01, May 2014 Information Collection and Reporting DODM 8910\_01\_Vol1, DoD Information Collections Manual: Procedures for DoD Internal Information Collections Air Force: AFI 38-501, Air Force Survey Program Army: Army Instruction 24 AUG 2016, Army Survey Approval Processes Navy: OPNAV 5300.8C, Coordination And Control Of Personnel Surveys; SECNAVINST 3900-39D, Human Research Protection Program