



DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER
503 ROBERT GRANT AVENUE
SILVER SPRING, MARYLAND 20910-7500

IN REPLY REFER TO:

NAVMEDRSCHCENINST 5721.1A
025
5 SEPT 2008

NAVMEDRSCHCENTER INSTRUCTION 5721.1A

From: Commanding Officer, Naval Medical Research Center

Subj: COMMAND PUBLICATIONS PROGRAM

Ref: (a) DoD Directive 3216.2
(b) SECNAVINST 5720.44B dated 01 Nov 2005
(c) BUMEDINST 5721.3B dated 08 Jan 2007
(d) NMSC ltr 5720 Ser 00/1138 of 14 Mar 06

Encl: (1) Request for Clearance for Publications and
Presentations Form: (V3.0:08.2008)
(2) NMSC Chain of Command Routing Sheet

1. Purpose. To promulgate procedures governing publication clearance process for the Naval Medical Research Center (NMRC) and its subordinate activities.

2. Cancellation. NAVMEDRSCHCENINST 5721.1 is hereby cancelled and superseded.

3. Background. Publications and Presentations are governed by standards and norms detailed in references (a) through (d), and include any authored work material that can be referenced or cited, such as journal articles, manuscripts, letters to the editor, case reports, published abstracts, book chapters and technical reports. Presentations consist of items for oral or visual presentation at a symposium or meeting. According to BUMEDINST 5721.3B authored work is defined as "any written document or oral presentation, both personal and professional, intending to be published to the general public. This includes any authored work that is to be transmitted via the internet, mass broadcast, or mass email where the general public may be able to obtain the authored work."

4. Scope. The requirements of this instruction are applicable to all NMRC and Echelon 5 and 6 authors, directorates and departments. Additionally, when a Material Transfer Agreement (MTA), Cooperative Research and Development Agreement (CRADA) or other research partner submits a publication for NMRC review as part of the terms of the agreement, the collaborating directorate

will initiate clearance procedures if there is no current NMRC associated investigator.

5. Responsibilities.

a. Naval Medical Research Center.

(1) The author will:

(a) Submit enclosure (1) at least 40 working days (10 for NMRC, 10 days for NMSC and 20 for BUMED) prior to submission date. Please note that all requests must be endorsed by the Navy Medical Support Command (NMSC) prior to submission to BUMED.

(b) Include the required statement(s) (i.e., Navy disclaimer, human or animal research, source of funding, and copyright) in the submitted authored work.

(c) Ensure final copies of accepted and cleared presentations are submitted to ORA one week prior to the date of the presentation or meeting.

(d) Forward manuscripts to ORA upon publication.

(2) The submitting directorate will:

(a) Conduct a substantive scientific and professional review.

(b) Ensure that the clearance request is complete.

(c) Ensure that the clearance request is submitted in a timely manner according to 5.a.(1)(a).

(d) Provide a synopsis (Attachment 1 - Publication Clearance Request (CPP - Form 1)) of the authored work to provide to NMSC.

(3) The Office of Research Administration (ORA) will:

(a) Verify that the submitted publication clearance request is completed accurately.

(b) Forward all clearance requests via the chain of command in a timely manner.

(c) Forward to the Bureau of Medicine and Surgery (BUMED) (M09B7) via NMSC all clearance requests that require higher authority review and approval.

(d) Forward to NMSC a copy of all locally approved abstracts and manuscripts for documentation purposes.

(e) Inform the author of the submitted clearance request status when the following occurs:

(1) Changes or additional information are required prior to submitting via the chain of command.

(2) The clearance request has been approved/disapproved by the Command.

(3) The clearance request has been forwarded to BUMED (M09B7C) via NMSC for higher review and approval.

(4) The clearance request has been forwarded by BUMED (M09B7C) to higher authority (Department of Defense (DoD), the Secretary of the Navy (SECNAV) or the Chief of Naval Operations (CNO)) for review and approval.

(5) The clearance request has been approved/disapproved by NMSC or BUMED (M09B7C).

(4) Director, Research Services will:

(a) Perform a secondary review of the clearance request.

(b) Ensure that the clearance request adheres to the standards regarding the protection and use of animals in research.

(5) Office of Intellectual Property/Office of Technology Transfer will:

(a) Ensure that the clearance request adheres to the standards regarding the protection and appropriate use of data/intellectual property and the standards regarding scientific misconduct.

(b) Confirm that the terms of the MTA, CRADA, or other agreements have been satisfied.

(c) Determine if patent issues or potential patent issues are involved.

(d) Provide Command ethics and legal review.

(6) Public Affairs Officer (PAO) will:

(a) Conduct a review to determine any potential media interest.

(b) Determine if higher authority review is required.

(c) With delegated authority from the Commanding Officer, Approve/disapprove clearance requests that do not require higher authority review.

b. NMRC Subordinate Echelon 5 and 6 Commands.

(1) Subordinate activity Commanding Officers/Officers-in-Charge will:

(a) Establish a publications program in accordance with references (a) through (d) and this instruction as applicable for the activity.

(1) Use enclosure (1) to request clearance or ensure that local forms incorporate all of the required elements from enclosure (1).

(2) If enclosure (1) is not used, route enclosure (2) with the local clearance request document.

(b) The Naval Medical Research Center Detachment (NMRCD) will submit all publication clearance requests through ORA for NMRC PAO approval.

(c) Forward a copy of all locally approved abstracts and manuscripts to NMSC via the chain of command.

(d) When higher authority review is required, all Echelon 5 and 6 activities will forward clearance requests to BUMED (M09B7C) or higher authority via the chain of command for endorsement.

6. Navy-Funded Research.

a. For programs where NMRC serves as administrator of funds to non-governmental researchers, institutions or programs (i.e., Advanced Medical Development programs, etc.), materials do not require higher level clearance unless 1) it addresses plans, policies, programs or operations of the DoD or the U.S. government, 2) is potentially or inherently controversial or likely to receive media coverage or publicity.

b. The material must still be cleared locally by the Commanding Officer or his designee. The point of contact should receive a courtesy copy of the authored work to review prior to its submission for publication to ensure that the material is cleared locally by the Command and the U.S. Government's interests are protected. The funding source statement should be included and the outside entity should be encouraged to include the disclaimer statement as provided in reference (c). Examples of such materials include peer reviewed publications or presentations before professional communities or organizations that do NOT contain subject matter involving items 1 and 2 above.

7. Forms. An electronic version of the required clearance form provided in enclosure (1) is available on the NMRC Internet Site (http://www.nmrc.navy.mil/RES_SVC/doc/Clearance_Form_v3.0.doc) and may be reproduced locally.



J. C. DANIEL

Distribution:
List(s) A, B, C and D

6. Activity involves *(select all that apply):*

Human Subject Research Protocol No.:

Project No.:

Projects that have been reviewed by the IRB Chair and determined to not meet the definition of human subjects research will have a "project number." Please refer to the form entitled, "Determination of Human Use Research Status," for further information.

Animal Use Research Protocol No.:

7. Is activity supported by a Grant, CRADA, MTA, NDA or other agreement: Yes No

If yes, please provide the following:

- **Grant/Agreement Type and No.:**
- **Grant/Agreement Sponsor Name:**
- **Grant/Agreement Title:**
- **Contractor/Collaborator/Recipient Name:**
- **Has the non-government party been given advance notice of publication required by the agreement prior to submission?** Yes No

8. Relevance of manuscript or presentation to operational medicine/Navy medicine:

9. Summary of media sensitive subject matter:

Part B – Synopsis in Layman’s Terms

Please also complete Part A of Attachment 1.

1. **Background:**
2. **Results:**
3. **Conclusions:**
4. **Sensitive areas/media interest:**

Part C – Purpose/Forum

Please also complete Part A of Attachment 1.

1. Journals *(please attach copies of submission)*

Journal title:

- Manuscript** **Letter to the Editor** **Case Report** **Other:**
 Domestic **Foreign** *(Country)*

2. Meeting/Conference *(please attach copies of submissions)*

Name, place and dates of meeting:

- Abstract for oral presentation/briefing** (submission deadline date)
 Abstract for poster/exhibit (submission deadline date)
Please submit an electronic copy of poster one week prior to departure.
 Keynote presentation (submission deadline date)
 Other, please explain:

3. Other (please attach copies of submissions)

- Book chapter, provide title of book, editor(s), publisher:**
- Technical report**

Part D – Required Disclaimers and Acknowledgments

Note on Abstracts: Because abstracts are usually limited to a specific word count and/or are used to determine whether the work will be accepted for publication or presentation, the required Navy disclaimers, acknowledgement of support, human and animal involvement statements are generally not included in the abstract. However, these statements should be included in the actual publication and/or presentation (e.g., posters, slides, etc.)

1. Disclaimer:

Publications and presentations for which an author claims Navy affiliation, the disclaimer provided below should be included. Further, manuscripts and professional articles completed in an official capacity or funded by the government shall identify the author with complete name, military grade, title and command.

The views expressed in this article are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government.

- Yes, page:**

2. Source of support (e.g., WUN):

All publications and presentations must disclose all sources of Navy funding, for example:

This work was supported by funded by work unit number xxxx.

- Yes, page:** **No, please explain:**

3. Human Research Protections/IRB statement:

All publications and presentations concerning research involving the use of human subjects must contain the following statement:

The study protocol was approved by the Naval Medical Research Center Institutional Review Board in compliance with all applicable Federal regulations governing the protection of human subjects.

- Yes, page:**
- No. If human research protocol number provided above please explain:**

4. Animal Care and Use statement:

All publications and presentations concerning research involving animals must contain such a statement.

The experiments reported herein were conducted in compliance with the Animal Welfare Act and in accordance with the principles set forth in the "Guide for the Care and Use of Laboratory Animals," Institute of Laboratory Animals Resources, National Research Council, National Academy Press, 1996.

- Yes, page:**
- No. If animal research protocol number provided above please explain:**

5. Copyright statement:

The copyright statement must be attached to all government work when submitted to civilian media for publication.

I am a military service member (or employee of the U.S. Government). This work was prepared as part of my official duties. Title 17 U.S.C. §105 provides that 'Copyright protection under this title is not available for any work of the United States Government.' Title 17 U.S.C. §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties.

- Yes, page:**

Part E – Author Attestation & OIC/Directorate Review

AUTHOR: I attest that the above information is correct and accurate to the best of my knowledge.

Signature: _____

Date: _____

Print Name:

Rank:

Print Title:

DEPARTMENT HEAD:

Signature: _____

Date: _____

Print Name:

LOCAL OIC/DIRECTORATE: This submission has received scientific review.

Signature: _____

Date: _____

Print Name:

Part F – Command Review

OFFICE OF RESEARCH ADMINISTRATION (ORA):

Signature: _____

Date: _____

Terri R. Brantley, Head, ORA

RESEARCH SERVICES DIRECTORATE (RSD):

Signature: _____

Date: _____

Adam E. McKee, DVM, Director, RSD

OFFICE OF TECHNOLOGY TRANSFER (OTT):

Signature: _____

Date: _____

Charles Schlagel, PhD, Head, OTT

OFFICE OF INTELLECTUAL PROPERTY (OIP):

Signature: _____

Date: _____

Joseph K. Hemby, Jr., Esq., Head, OIP

PAO/COMMAND:

Check all of the following items that apply to this publication or presentation:
 If a "yes" option is selected, higher review is required pursuant to BUMEDINST 5721.3B

Yes	NO	
<input type="checkbox"/>	<input type="checkbox"/>	Non-human primates, cats, dogs or marine mammals
<input type="checkbox"/>	<input type="checkbox"/>	International Media
<input type="checkbox"/>	<input type="checkbox"/>	AIDS/HIV
<input type="checkbox"/>	<input type="checkbox"/>	Controversial or sensitive
<input type="checkbox"/>	<input type="checkbox"/>	Potential media interest
<input type="checkbox"/>	<input type="checkbox"/>	Addresses government policy or findings more appropriately released by the Seat of Gov't
<input type="checkbox"/>	<input type="checkbox"/>	Special Research Topic (e.g., Persian Gulf, Women's Issues, PTSD, etc.)
<input type="checkbox"/> Cleared (select if review by higher authority <i>not</i> required)		
<input type="checkbox"/> Cleared at NMRC Only – Requires Higher Review & Clearance		

Signature: _____

Date: _____

Eric R. Hall
 CDR, MSC, USN
 NMRC, PAO

Email Address: Eric.Hall@med.navy.mil

Telephone: 301-319-7581



ORA Use Only
File No.

Part A – NMSC PAO Synopsis

NOTE: Investigators complete this section and submit as an attached Word Document. The document should include Title, presentation/publication type, where and when it is to be published/presented (if known). Tracking information (number) will be assigned by NMRC.*

SAMPLE (Use the following example as your guide).

NHRC 08-310*

Morphine Use after Injury Protects Against PTSD Onset: Findings From the Navy Marine Corps Combat Trauma Registry Deployment Health Database. This is an article that will be submitted to JAMA for an upcoming issue yet to be determined.

SYNOPSIS: This report's objective was to examine the effect of morphine use during early resuscitation and trauma care on PTSD onset in injured military personnel. These results provide new evidence that morphine or other compounds may protect against the development of PTSD after serious injury. These findings have important implications for future pharmacological interventions to reduce PTSD incidence after serious injury and exposure to traumatic events. They have the potential to wield a profound impact on PTSD prevention and provide a foundation for continuing to improve 21st century trauma care.

NMSC Chain of Command Routing

Originating Command Public Affairs completes this section:

<input type="checkbox"/> Command Public Affairs has approved for submission/presentation. No higher review required. Abstract forwarded via the chain of command to NMSC for documentary purposes	Date:
<input type="checkbox"/> Higher review required. Command Public Affairs has forwarded electronically via the chain of command for higher review.	Date:
<input type="checkbox"/> Author notified of higher review results	Date:

Echelon 5 Command Public Affairs (if applicable*) completes this section:

<input type="checkbox"/> Command Public Affairs has approved for submission/presentation. No higher review required. Abstract forwarded via the chain of command to NMSC for documentary purposes	Date:
<input type="checkbox"/> Higher review required. Command Public Affairs has forwarded electronically via the chain of command for higher review.	Date:
<input type="checkbox"/> Command Public Affairs has received results of higher review	Date:
<input type="checkbox"/> Command Public Affairs has notified originator	Date:

*if originating command is an echelon 5 command omit this section

Echelon 4 Command Public Affairs (if applicable*) completes this section:

<input type="checkbox"/> Command Public Affairs has approved for submission/presentation. No higher review required. Abstract forwarded via the chain of command to NMSC for documentary purposes	Date:
<input type="checkbox"/> Higher review required. Command Public Affairs has forwarded electronically via the chain of command for higher review.	Date:
<input type="checkbox"/> Command Public Affairs has received results of higher review	Date:
<input type="checkbox"/> Command Public Affairs has notified originator	Date:

*if originating command is an echelon 4 command omit this section

NMSC Public Affairs completes this section:

<input type="checkbox"/> NMSC Public Affairs has approved for submission/presentation. No higher review required. Originator notified via the chain of command.	Date:
<input type="checkbox"/> Higher review required. NMSC Public Affairs has forwarded electronically via to BUMED for higher review.	Date:
<input type="checkbox"/> NMSC Public Affairs has received results of higher review	Date:
<input type="checkbox"/> NMSC Public Affairs has notified originator via the chain of command	Date:

BUMED Public Affairs completes this section:

<input type="checkbox"/> BUMED Public Affairs has approved for submission/presentation	Date:
<input type="checkbox"/> BUMED Public Affairs has forwarded for higher review	Date:
<input type="checkbox"/> BUMED Public Affairs has received higher review	Date:
<input type="checkbox"/> BUMED Public Affairs has notified NMSC of review results	Date:

Enclosure (2)