

OFFICE OF THE
DIRECTOR MARINE CORPS STAFF



| CODE | RTG | INITIAL | REMARKS |
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| CMC | | | |
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| DMCS | 3 | GW 9/21 | |
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| EDITOR | X | J 9-19 | COORDINATION @ Tab B. |
| CL | | | |

MCATS ID: 2012-9-22754

Subj: ESTABLISHMENT OF A SINGLE INSTITUTIONAL REVIEW BOARD TO SUPPORT MARINE CORPS HUMAN RESEARCH PROTECTION PROGRAM ACTIVITIES

Purpose: Obtain DMCS approval to establish a single Institutional Review Board (IRB) to provide review services and HRPP support for all HQMC sponsored research and other human subject research involving Marines, Marine Corps family members and Marine Corps civilian employees.

Background. MCO 3900.18 established the Marine Corps HRPP with DC CDI as the Marine Corps lead. CG MCCDC established an HRPP with the Executive Deputy TECOM as the Institutional Official. One year of operation of this IRB and monitoring human subject research activities across the Marine Corps in coordination with the DON HRPP office resulted in the conclusion that the Marine Corps HRPP support can be provided by a single IRB.

Discussion: The MCCDC IRB is currently the only approved Marine Corps IRB and has a staffed HRPP. The MCCDC IRB is being asked to conduct applicability and other HRP related reviews on behalf of other Marine Corps entities without a formal relationship or authority to do so. Subject proposal will streamline the Marine Corps HRPP process and provide a formal HSR review relationship for Marine Corps commands and HQMC.

Recommendation: DMCS approve establishment of a single IRB as proposed.

Prepared by: Mr. Jeff Tabb, DMCS Support, (703) 697-1043

PRIVACY SENSITIVE

ANY MISUSE OR UNAUTHORIZED DISCLOSURE MAY RESULT IN BOTH CIVIL AND CRIMINAL PENALTIES

HEADQUARTERS MARINE CORPS ROUTING SHEET (5211)

NAVMC HQ 335 (REV. 04-07)

Revised: 20110929

| 2 OPERATION CODE | | | | | | 1 DATE: 2/8/2012 | | | | |
|--|--------|--------------------|--|--------|--|---|--|--|---|-------------------|
| X - ORIGINATOR OF OFFICE AFFIXING ROUTING SHEET A - APPROPRIATE ACTION B - GUIDANCE C - SIGNATURE D - COMMENT E - RECOMMENDATION F - CONCURRENCE | | | G - INFORMATION H - RETURN TO: MCCDC HRPO I - INITIAL J - DISPOSITION K - DECISION L - RETENTION O - (OTHER) | | | 3 SUBJECT: ESTABLISHMENT OF A SINGLE HEADQUARTERS MARINE CORPS (HQMC) INSTITUTIONAL REVIEW BOARD (IRB) TO SUPPORT MARINE CORPS HUMAN RESEARCH PROTECTION PROGRAM (HRPP) ACTIVITIES | | | | |
| ROUTING - Use numbers to show order of routing | | | | | | | | | | |
| 4 RT | 5 CODE | 6 ADDRESSEES | | 7 DATE | | 8 INITIALS | | 9 NATURE OF ACTION REQUIRED | ORIGINATOR'S INITIALS | DUE DATE (If any) |
| //// | | COMMANDANT | CMC | | | | | ROUTINE | LBW | 2/28/2012 |
| //// | | MILITARY SECY | MILSEC | | | | | URGENT | | |
| //// | | ASST COMMANDANT | ACMC | | | | | 10 REMARKS AND SIGNATURE (If additional space is necessary, attach plain paper) Tab A: USMC HRPP Information Paper Ref: MCO 3900.18 1. PURPOSE. Request addressee comments on the recommendation to have a single Institutional Review Board (IRB) provide review services and HRPP support for all HQMC sponsored research and other human subject research involving Marines, Marine Corps family members and Marine Corps civilian employees. 2. BACKGROUND. Reference MCO established the Marine Corps HRPP in January 2011, with DC CDI as the Marine Corps lead. Per the MCO, CG MCCDC established an HRPP, with the Executive Deputy TECOM as the Institutional Official, the CG's direct representative for its HRPP. 3. DISCUSSION - One year of operation of the MCCDC IRB, and monitoring human subject research activities across the Marine Corps in coordination with the Department of the Navy (DON) HRPP office, has resulted in the conclusion that the Marine Corps HRPP support can be provided by a single IRB. - The MCCDC IRB is currently the only approved Marine Corps IRB and has a staffed HRPP. The MCCDC IRB is being asked to conduct applicability and other HRP related reviews on behalf of other Marine Corps entities without a formal relationship or authority to do so. - <u>Subject proposal will streamline the Marine Corps HRPP process and provide a formal HSR review relationship for Marine Corps commands and HQMC.</u> - Comments in response to this MCATS tasker will be consolidated and draft changes to the MCO will be staffed to DC CDI for consideration. 4. RECOMMENDATION. Request comment or concurrence via MCATS response, with responses due by 28 February 2012. | | |
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| | | | | | | | | | 11 ACTION OFFICER (Name, Grade, Office Code, Telephone number) Leah B. Watson, GS-14, MCCDC HRPO and IRB Chair, 703-432-2566 | |

UNCLASSIFIED

Tab
A



UNITED STATES MARINE CORPS
MARINE CORPS COMBAT DEVELOPMENT COMMAND
3300 RUSSELL ROAD
QUANTICO, VIRGINIA 22134-5135

3900
C-4623
30 Jul 12

DECISION PAPER

Subj: Establishment of a Single Headquarters Marine Corps (HQMC)
Institutional Review Board (IRB) to Support HQMC Human Research
Protection Program (HRPP) Activities

Ref: (a) MCO 3900.18

Encl: (1) Endorsements of HQMC Agencies and Deputy Commandants (DCs)

1. Purpose: To obtain the Director Marine Corps Staff (DMCS) concurrence to establish a single, centralized, HQMC IRB for the protection of human subjects in research by designating the Marine Corps Combat Development Command (MCCDC) IRB as the HQMC IRB.

2. Requirement: MCO 3900.18 (21 January 2011) directed the establishment of a USMC Human Research Protection Program (HRPP). Eighteen months of experience has demonstrated that a single HQMC-level IRB is adequate for review of Marine Corps social, behavioral, educational (SBE) and developmental, test, and evaluation (DTE) research.

3. Background/Discussion

a. Marine Corps research involving human subjects is conducted primarily at MCCDC, including its subordinate commands and directorates (Marine Corps Warfighting Lab, Training and Education Command, Marine Corps University, Marine Corps Center for Lessons Learned, Center for Advanced Operational Culture Learning) and by HQMC activities including Manpower and Reserve Affairs, Marine Corps Systems Command, Marine Corps Intelligence Activity, and Marine Corps Operational Test and Evaluation Activity. Plans, Policy and Operations, Installation and Logistics, the Inspector General of the Marine Corps, Intelligence Division, Marine Corps Forces Command, Marine Corps Forces Pacific and the Marine Corps Expeditionary Forces could also be served by the single IRB.

b. A single IRB is sufficient to meet the expected workload and provides the most economic use of Marine Corps resources.

c. The MCCDC IRB, established 10 December 2010 and already fully staffed, can serve as the single IRB for review of USMC research involving human subjects. The MCCDC IRB has served in this capacity since it was established. The Executive Deputy, Training and Education Command is appointed as the MCCDC Institutional Official and is delegated the authority to act for CG, MCCDC on all HRPP matters.

d. Additional IRB members will be solicited from HQMC organizations to ensure that representation and subject matter experts support protocol review requirements. Currently the MCCDC IRB has members from M&RA, MCIA and MCSC.

e. All biomedical research involving human subjects will continue to be reviewed by appropriate Navy Medicine IRBs and coordinated through HQMC Health Services.

f. The Deputy Commandant for Combat Development and Integration (DC CD&I) serves as the coordinating authority for HRPP within the Marine Corps. When approved, this decision will be forwarded to DC, CD&I IOT change MCO 3900.18 to reflect designation of the MCCDC IRB as the single HQMC IRB.

4. Position of other agencies/units: The Department of the Navy, Office of Naval Research, Human Research Protections Office (DON HRPP) initiated this proposal to better support Marine Corps human subject research without additional structure or multiple IRBs. This proposal has been routed to HQMC staff agencies and Deputy Commandants, and received concurrence from all concerned.

5. Decision: Recommend the DMCS approve this recommendation.

6. Action Officer: Ms Leah Watson
Human Research Protection Official
Marine Corps Combat Development Command
703-432-2566

Prepared by: Dr. Andrew Jones, ONR 343, 703-588-0612

Approved by: SES Jeffery Bearor, TECOM, 703-432-2091

DECISION MATRIX

DMCS:

Approved

CPW 9/21/12

Disapproved

Tab
B

COORDINATION PAGE

Subj: ESTABLISHMENT OF A SINGLE HQMC INSTITUTIONAL REVIEW BOARD TO SUPPORT THE MARINE CORPS HUMAN RESEARCH PROTECTION PROGRAM ACTIVITIES

| <u>STAFF/EXTERNAL AGENCY</u> <u>(Note 1)</u> | <u>NAME</u> <u>(Note 2)</u> | <u>DATE & POSITION</u> <u>(Note 3)</u> |
|---|--------------------------------------|---|
| CL | Capt Repair | 31 May 12; concur |
| DC CD&I/CG MCCDC | LtGen R. P. Mills CG and DC CD&I | 13 Aug 12; concur |
| DC PP&O | Initials PAC | 10 Feb 12; no equity |
| DC I&L/CG MCICOM | GS-15 R. Stauffer/ GS-15 C. Smith | 5 Mar 12; concur |
| DC M&RA | Mrs. Sheryl Murray | 15 Aug 12; concur as long as there is M&RA Rep on the IRB |
| DC P&R | Ms Julie St.Onge | 22 Mar 12; no equity |
| Dir C4 | GS-14 Terry Bruning | 16 Mar 12; concur |
| SJA | Maj M. R. Renz | 19 Mar 12; concur |
| IGMC | GS-15 Carl Shelton | 23 Mar 12; concur; IGMC supports this initiative |
| Dir Intel | GS-15 Mark Silver | 13 Mar 12; concur |
| HS | CAPT Bill Padgett | 20 Mar 12; concur |
| Dir SD | Rich Coyle, Dep Dir | 15 Aug 12; concur |
| MARCORSYSCOM | GS-15 D. Karcher | 22 Mar 12; concur |

NOTES

1. List all internal and external agencies/commands you coordinated with using the appropriate abbreviated agency/command title.
2. Enter grade and name of the individual who approved/provided response, or "None Obtained" when an agency/command does not respond.
3. Enter one of the following, as appropriate:
 - "DD MMM YY - Concur" (if comments provided, attach them on next page)
 - "DD MMM YY - Nonconcur - see attached" (attach comment(s) on next page)
 - "Delivered DD MMM YY
No response as of DD MMM YY"