USAMRMC STRATEGIC COMMUNICATION PLAN

OFFICE OF RESEARCH PROTECTIONS (ORP)

MISSION

The Office of Research Protections assures that research conducted, contracted, sponsored, supported, or managed by USAMRMC, as well as any U.S. Army Medical Command clinical investigations involving human subjects, human anatomical substances, or animals, are conducted in accordance with federal, DoD, Army, USAMRMC, and international regulatory requirements.

BACKGROUND

The Human Research Protections Office (HRPO) is tasked with ensuring all investigational activities conducted within USAMRMC and MEDCOM are in accordance with government regulations.

They are responsible for the following:

- **Serving as the principal advisor** to the Command for human subjects protection.
- **Developing and implementing** human subjects protection policies and regulations.
- **Maintaining** the USAMRMC Volunteer Registry Management System.
- **Reviewing and approving** intramural and extramural human subject protocols.
- **Conducting site visits** to ensure that human subjects are adequately protected.

The IRBO (Institutional Review Board Office) was established in May 2010 and serves a component of the USAMRMC Human Research Protections Program. The IRBO supports the activities of the USAMRMC IRB to provide review, approval, and oversight for human

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research conducted by scientists assigned to USAMRMC, at select USAMRMC subordinate institutes and laboratories, at select non-USAMRMC DoD institutions, and in support of the DoD's Force Health Protection Program.

The Clinical Investigations Review Office (CIRO) provides regulatory oversight for the MEDCOM Clinical Investigation Program (CIP) and provides education to MEDCOM IRBs and Department of Clinical Investigation. The Army CIP improves health care and facilitates graduate medical education, graduate dental education, and other professional health education by stimulation of scholarly endeavor, retention of faculty, and introduction of new technology.

The Animal Care and Use Review Office (ACURO) reviews animal use proposals contracted or sponsored by MEDCOM and select DoD agencies to ensure research or training using animals is conducted in accordance with applicable laws and regulations. The ACURO ensures compliance with animal welfare laws and regulations at USAMRMC and MEDCOM facilities conducting research or training using animals through compliance inspections and protocol review. The ACURO directs the U.S. Army Laboratory Animal Medicine Residency Program, a postdoctoral training program for Army veterinarians approved by the American College of Laboratory Animal Medicine.

The ORP's website offers a complete lists of regulations, policies, and procedures for each of the four subordinate offices.

QUESTIONS & ANSWERS

Q *What are some of the most significant achievements of the ORP?*

A The ORP serves as DoD subject matter experts in human research protections and animal care and use in research. It provides regulatory education to the Army and DoD. It is the home of the Army Lab Animal Medicine Residency. Headquarters (HQ) USAMRMC IRB serves as the IRB for many DoD organizations to include USCENTCOM. It provides HQ-level regulatory review for more than 6,000 studies, to include research in more than 1,400 institutions and 40 countries with dedication to facilitation of research that adheres to ethical standards and complies with regulatory requirements.

KEY THEMES AND MESSAGES

The ORP provides guidance on USAMRMC human subjects protection and animal welfare policies and procedures, develops educational activities for persons conducting or managing research, and implements an active compliance oversight program.

The ORP has four major subordinate offices: the HRPO, the CIRO, the IRBO, and the ACURO.

Questions regarding the use of animals for combat trauma or chemical casualty training should be referred to the MEDCOM Public Affairs Office.

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Q ***What are some of the key initiatives for the ORP?***

A Initiatives include: promotion of economies of IRB review, support for research in the combat theater of operations, proponent for automated IRB systems, web-mediated education programs, and streamlining HQ-level review processes for all categories of research.

Q ***Are there any opportunities for the information, tools, or systems that have been obtained or developed by the ORP to be translated for civilian use?***

A Use of our international human subjects protection checklists and site-specific addendum forms are one example.

Q ***How do you ensure that researchers and labs are compliant?***

A The ACURO ensures that the care and use of animals in research, development, testing, evaluation, and training in Army laboratories is compliant through staff assistance visits, compliance inspections, and administrative review of animal use protocols. HRPO, IRBO, and CIRO ensure that human research protocols are implemented in accordance with regulatory requirements via protocol review, continuing review, site visits, required reporting of threshold events, inspections, and audits.

Q ***Are all facilities currently compliant? If a lab or a researcher is in violation, is that information shared with the public?***

A All USAMRMC and MEDCOM facilities using animals in research or training are compliant and accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). If noncompliances are identified, AAALAC is notified as well as the Office of Laboratory Animal Welfare if the institution holds a Public Health Service Animal Welfare Assurance. The ACURO also reports noncompliances to the Office of the Assistant Secretary of Defense for Research and Engineering. All USAMRMC and MEDCOM institutions conducting human subjects research hold current DoD Assurances for Human Subjects Research Protections.