Report No. SPO-2011-005 (Project No. D2009-D00SPO-0242.00) March 31, 2011

Results in Brief: Assessment of Allegations Concerning Traumatic Brain Injury Research Integrity in Iraq

What We Did

This assessment was initiated in response to allegations brought to the attention of the Department of Defense, Office of Inspector General, concerning the integrity of a traumatic brain injury research project in Iraq. The overall objective of the assessment was to review these allegations and determine whether:

- DoD guidance regarding the performance of research on human subjects (in this case deployed, injured U.S. Military personnel in Iraq) was violated in a DoD-approved clinical research trial evaluating a treatment for mild traumatic brain injury.
- Research misconduct occurred during this specific DoD-approved clinical research trial.

We visited organizations, conducted interviews, and reviewed records and standards pertinent to the conduct and oversight of the research protocol, "The Use of Anti-Oxidants to Reduce Sequela of Mild Traumatic Brain Injury (mTBI) After Blast Exposure," conducted at Camp Al Taqaddum, Iraq, between December 2008 and March 2009. We considered both U.S. Navy and U.S. Army regulations, because the Principal Investigator for this research was a U.S. Navy physician, and since the U.S. Army Surgeon General approved the DoD Assurance of Compliance for the Multi-National Corps – Iraq, setting standards for the conduct of human-subject medical research in Iraq.

What We Found

We identified the following principal concerns:

- The management and conduct of the clinical trial were inconsistent with military standards for human subject medical research
- Possible sub-standard patient care
- Weaknesses in the process used to review and approve medical research in Iraq

What We Recommend

The Under Secretary of Defense for Acquisition, Technology and Logistics:

- Update relevant medical research policies to ensure that procedures are in place to adequately protect the rights of deployed personnel from coercion and undue influence to participate in research studies.
- Coordinate with the Military services to ensure DoD and Service level medical research policies are pertinent to research conducted in a joint-service environment. Specifically ensure there are clear lines of accountability and responsibility for the investigation of alleged research misconduct which may involve more than one Military service.

The Assistant Secretary of Defense for Health Affairs:

- Conduct health assessments to determine if there were any adverse effects on the health of the U.S. Service members who participated in the mTBI clinical trial.
- Coordinate a review of the Joint Theater Trauma System (JTTS) Clinical Practice Guideline (CPG) "Management of Mild Traumatic Brain Injury (mTBI)/Concussion in the Deployed Setting."

The U.S. Army Medical Command:

- Investigate potential medical research misconduct by a U.S. Navy physician and take appropriate action as required.
- Update relevant policies and procedures to ensure a standardized approach to the conduct of medical research that provides an appropriate standard of protection for the rights and welfare of research participants.

What We Recommend (cont.)

The U.S. Army Medical Command (cont.):

- Ensure that procedures are in place to adequately address the use of nutritional supplements as investigational drugs.
- Ensure individuals involved in medical research receive training in the use of investigational drugs and applicable FDA regulations.
- Conduct a review of the Institutional Review Board's deliberations which resulted in the approval of the research protocol.
- Conduct a review of the Deployed Combat Casualty Research Team's report which evaluated the research at Camp Al Taqaddum.

The U.S. Navy Bureau of Medicine and Surgery:

- Identify the research participants and conduct a Quality of Care Review to determine whether these Military service personnel received appropriate medical care.
- Update relevant policies and procedures to ensure a standardized approach to the conduct of medical research that provides an appropriate standard of protection for the rights and welfare of research participants. Ensure that procedures are in place to adequately address the use of nutritional supplements as investigational drugs.
- Ensure all individuals involved in clinical research receive training in the use of investigational drugs and Food and Drug Administration regulations.

Management Comments and Our Response

Under Secretary of Defense for Acquisition, Technology and Logistics (USD [AT&L]):

The Assistant Secretary of Defense for Research and Engineering, responding on behalf of USD(AT&L), generally concurred with our recommendations and has taken action to update draft DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research" accordingly.

U.S. Army Medical Command (USAMEDCOM):

The Commanding General, USAMEDCOM generally concurred with our recommendations. We commend the Commanding General and his staff for proactively implementing corrective actions for many of the recommendations, and agreeing to take additional actions within the next several months. Furthermore, we appreciate their willingness to complete an investigation into all allegations of potential research misconduct.

U.S. Navy Bureau of Medicine and Surgery (BUMED):

BUMED concurred with several recommendations and plans to take corrective action.

~~(FOUO)~~ [redacted] Consequently, we requested that the Assistant Secretary of Defense for Health Affairs conduct the necessary health assessments.

~~(FOUO)~~ [redacted] Consequently, we revised the recommendation and requested that the U.S. Army complete any necessary investigation.

Additional Recommendations: We added several recommendations due to management comments. We request that the Assistant Secretary of Defense for Health Affairs and the Commanding General, U.S. Army Medical Command provide additional comments to the final report by May 6, 2011. Please see the recommendations table on the next page.