

# Recommendations for Civilian Investigators Conducting Human Studies in the Military

Craig Formby, Ph.D.

Distinguished Graduate Research Professor Emeritus

University of Alabama

Auburn University October 4, 2019

# Recommendations

1. Work closely with knowledgeable and enthusiastic military officials to identify appropriate study sites
2. Obtain commitments for the study from enthusiastic site investigators and as much of the full chain of command as possible before requesting funding
3. Because of the transitional nature of the military, anticipate greater participant attrition and missed study visits than for corresponding studies conducted in civilian clinical centers; therefore, power your study accordingly and anticipate a longer study duration to achieve the target study sample

# Recommendations

4. After funding is attained, initiate processes early on to prepare Cooperative Research and Development Agreements (CRADAs) and to obtain IRB approvals (simultaneously, if allowed ); be prepared to be patient with these processes
5. Recruit and cross train study personnel, providing for redundancy in key study personnel
6. Consider hiring civilian study staff, but be prepared for lengthy intervals between hiring and approval of their security clearances

# Recommendations

7. Anticipate ongoing training of study personnel due to the transitional nature of military personnel
8. For long-term studies, plan for continued care and data collection after study participants are reposted or after they separate from the military and can no longer be treated at a military facility
9. Plan flexible recruitment strategies in anticipation that each study site may have different and changing requirements for posting and allowing for recruitment materials to be dispersed

# Recommendations

10. Anticipate challenges transferring study data through clinical center firewalls, which may limit the utility of web-based data systems and off-site repositories
11. Anticipate challenges arranging for base access and expect delays when entering military study sites
12. Anticipate challenges paying civilian study personnel, purchasing study equipment and supplies, and arranging study-related travel within the military system

# Recommendations

13. Be prepared for military priorities to take precedence over study protocols, especially last minute cancellation of study visits
14. Expect the unexpected-wars, furloughs, base closures, restrictions affecting study participation, transfers of study personnel and participants, change in military priorities and site/command commitments leading to loss of study sites

# Acknowledgements

This presentation was adapted from “*Lessons learned conducting a multi-center trial with a military population: The Tinnitus Retraining Therapy Trial*”, Clinical Trials, published online, May 2018. (Available as a handout)

Support for preparation of the above report was provided by NIH awards U01DC007411 (C. Formby, Study Chair) and U01DC007422 (R.W. Scherer, Data Coordinating Center Director).