59 MDW Research Reference Guide

59th Medical Wing
Office of the Chief Scientist
Science and Technology
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INTRODUCTION

The purpose of the Principle Investigator Handbook is to aid researchers in planning, proposing, preparing, funding, executing; and reporting research and program initiatives conducted by the 59th Medical Wing (59 MDW) and overseen by the Office of the Chief Scientist (59 MDW/ST) and the Science and Technology Office (ST). Additionally this handbook serves as a guide for new investigators as well as more experienced investigators in their search and submission efforts for other funding opportunities. This guide is not intended to be all-inclusive due to the frequency of program announcements and associated process and policy changes; as such, investigators are encouraged to contact the appropriate office for additional support. The majority of this resource is designed to give the researcher an overview of the strategic emphasis (thrust areas, types of money, research processes, etc.) and a more detailed explanation of areas directly impacting them (e.g., research proposal development, protocol formats, suspense dates, briefings, contracts, etc.). The 59 MDW/ST staff pledges to do all that it can to assist you—investigators and directors—with the development and execution of your proposals, initiatives, projects, and programs.

PURPOSE

All Air Force research (clinical research and clinical studies) conducted within the Military Health System (MHS)—irrespective of funding type and source—is overseen by the Office of the USAF Surgeon General Research Oversight and Compliance Office (AFMSA/SGE-C). Funding resources for Air Force research is overseen by the Headquarters Air Force Research and Acquisition (AF/SG 3/5) and Air Force Medical Support Agency Research and Acquisition Directorate (AFMSA/SRG5), for Air Force Medical Service (AFMS) Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E); and Operational and Maintenance (O&M) funds. Furthermore, SG5 oversees execution of research monies from the Office of Assistant Secretary of Defense Health Affairs (OASD/HA), Defense Health Agency (DHA) and the Joint Program Committee Chairs for the Defense Medical Research and Development Program (DMRDP). There are other sources of funds within the Department of Defense such as Service Line organizations (e.g., Office of Naval Research, Defense Advanced Research Program Agency (DARPA), Defense Threat Reduction Agency (DTRA), Defense Veterans Brain Injury Center (DVBIC)) as well as other federal (e.g., National Institutes of Health, Department of Health and Human Services), Congressional, state, and private funding. ST supports investigators with identifying funding opportunities to best fit their research focus and proposal. The 59 MDW Chief Scientist has the responsibility to oversee all research involving 59 MDW personnel, whether at the Wilford Hall Ambulatory Surgical Center (WHASC) or other sites, as applicable.

Research conducted within the Air Force should address gaps within the six (6) Air Force Surgeon General Modernization Thrust Areas. These thrust areas are managed by AFMSA/SRG5, whose mission is to apply science and technology to produce solutions to address identified needs. Research performed in these thrust areas are able to compete for research monies from multiple sources. These thrust areas are:

1. **Force Health Protection**
   Prevention of injury/illness and the early detection of emerging threats.

2. **En Route Care**
   Continuum of care during transport of patients from point of injury to point of definitive care.

3. **Operational Medicine/In-Garrison Care**
   Providing definitive patient care/treatment in-garrison.

4. **Human Performance**
   Enhancing performance of Airmen in challenging environments.

5. **Innovations (rolled into Operational Medicine)**
   Identify, evaluate, and develop novel concepts, new processes, or disruptive technologies.

6. **Expeditionary Medicine**
   Improving care during contingency operations; and medical countermeasures against combat/operational stressors.

For further details, please refer to Appendix A.
AFMS RDT&E funding is focused on addressing unique AFMS and Major Command (MAJCOM) scientific needs and material gaps as defined by formal Capability Based Assessments (CBAs). The 59 MDW/ST maintains a research work plan with projects aligned with AFMS programs to address those needs and gaps, serves as the major clinical and translational research execution platform for the AFMS, and engages directly with SG5 in the AFMS Corporate Process (Appendix B). Intramural calls for proposals will be released throughout the fiscal year which typically align with the thrust areas to guide investigator submissions.

The AFMS and OASD/HA also promote graduate health sciences education (GHSE) through the Clinical Investigation Program (CIP), overseen by AFMSA/SG5 and managed by AFMS CIP sites. The primary aim of the CIP is to improve the quality of healthcare for U.S. Department of Defense (DoD) warfighters, their families, and beneficiaries by generating an atmosphere of scientific inquiry, promoting an academic environment of high professional standing, and providing a means to assist in the accreditation of graduate medical education and other health training programs. These programs provide additional support to graduate medical education research efforts. More information on the 59 MDW Clinical Investigations Program can be found on AFMS Knowledge Exchange: https://kx2.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx.

The mission of the 59 MDW/ST is to conduct clinical studies and translational research and apply knowledge gained to enhance performance, protect the force, advance capabilities across the global health system, and train future medical leaders.” The goal of the 59 MDW research program is to advance the state of medical science in areas of the most pressing need and relevance to today’s battlefield and across-the-continuum of care experience. The 59 MDW Research Lanes: (1) Trauma, Resuscitation, and Stabilization; (2) Advanced Diagnostics and Therapeutics; (3) Clinical and Rehabilitative Medicine; (4) Medical Modeling and Simulation Training; and (5) Clinical Investigation Program, comprise the Research Portfolio and align with the AFMS Modernization Thrust Areas (MTAs) and Joint medical research programs (Appendices A, B and C). Nursing and Dental Wing research objectives are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities to accelerate the transition of medical technologies into deployed products; and to accelerate translation of advances in knowledge and technologies into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in-theater or in the clinical facilities of the 59 MDW, San Antonio Military Health System (SAMHS), DHA, and MHS in the deployed and in-garrison environment to address AFMS and MAJCOM capability gaps. The 59 MDW research program supports the 59 MDW mission to “develop warrior medics through patient-centered care” by providing direct support to Wing medical readiness, education and training programs, and continually improving patient care. In coordination with the CIP, the RDT&E program enables mentoring of GHSE students and staff researchers and training of investigators in the use of various types of funds to address Service-unique and Joint medical needs.

In addition to AFMS research efforts, the Department of Defense has its own research infrastructure with its own broad thrust areas. The DMRDP is a core DHP research program of the DoD and is housed within OASD/HA. The DMRDP serves as the focal point for execution of RDT&E funds that are awarded by the Joint Program Committees (JPC) via the U.S. Army Medical Materiel and Development Agency (USAMMDA). The seven (7) major research areas managed by the DMRDP are listed below:

1. JPC1 – Medical Simulation Training & Informatics
2. JPC2 – Military Infectious Disease
3. JPC5 – Military Operational Medicine
4. JPC6 – Combat Casualty Care
5. JPC7 – Medical Radiological Defense
6. JPC8 – Clinical & Rehabilitative Medicine
7. JPC9 – Advanced Development

For further details, please refer to Appendix B.
A core function of 59 MDW/ST is to facilitate clinical research to satisfy the aforementioned knowledge and technology gaps. Consequently ST has a critical role in the “lifecycle” of all clinical research that is performed within the MHS. The 59 MDW is one of two major research execution platforms and the largest clinical and translational research activity in the AFMS. ST receives and executes research funds and provides expert assistance to define Service-unique capability gaps, identify requirements-based, thrust area-aligned research, and conduct and manage research programs and projects. ST conducts research and provides assistance through the acquisition of people and materials to ensure investigators across the 59 MDW and other sites world-wide are able to complete their research and provide deliverables to fill capability gaps. Additionally, ST assists investigators in obtaining funding of all clinical studies and analyses, basic-to-applied research, advanced development, testing, sustainment, and fielding a product. ST enables best practices, innovation, education, training, translational research, and moving scientific findings to the operational environment and patient care setting.

**RESEARCH LIFECYCLE (Figure 1)**

![Research Lifecycle Diagram]

- **IDEA**
  - Literature Search
  - **Items to Consider:**
    - CRADA
    - MTA, DUA, NDA, MOU, CRU, etc.
    - FDA Approval
    - NIH, OBA-RAC, IBC Review
    - Funding

- **PROTOCOL**
  - Human Study
    - IRB
    - CITI
  - Animal Study
    - IACUC
    - AALAS

- **Research Training**

- **Presentation to Committee**
  - Protocol Approved
  - Post-Approval Documents
    - Progress Reports
    - Amendments
    - Adverse Event Report
    - Annual Report
    - Final Report

**Initial Consultation with CRD Laboratory Animal Medical Officer (LAMO)**

Investigators interested in developing an animal use research protocol should first meet with the CRD LAMO to determine whether the CRD animal facility can support the appropriate animal model. If the proposed research cannot be accomplished at the CRD, it may be possible for the LAMO to assist the researcher in locating an alternate animal use facility that can support the research.

*Must have PA approval – 59 MDW Form 3639*
Protocol Development

Investigators and the research team are required to comply with the regulatory requirements governing all human and animal research, as applicable to their study. Research Compliance Office is housed at the 59 MDW/ST Clinical Research Division (CRD). Research related templates (e.g., research protocols, HIPAA, Informed Consent Document, etc. documents) required to obtain approval for human or animal research are regularly updated and available through the Office of Research Protocol Support either by emailing your request to 59crd.protocol@us.af.mil or through the AFMS Knowledge Exchange: (https://kx2.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx).

Approval for research involving human subjects is granted by the 59 MDW Institutional Review Board (IRB). Approval for animal research studies is granted by the 59 MDW Institutional Animal Care and Use Committee (IACUC). It should be noted in most cases IACUCs are tied to the facility in which the animal use will be conducted. Both the IRB and the IACUC are housed at the CRD. The Brooke Army Medical Center (BAMC) IRB is housed at the San Antonio Military Medical Center (SAMMC), Department of Clinical Investigations (DCI); and the IACUCs are located at the U.S. Army Institute for Surgical Research and the Tri-Service Research Laboratory at Fort Sam Houston. Additionally, some investigator protocols will go to the U.S. Army Medical Research and Materiel Command (USAMRMC) IRB for review (e.g., protocols with research conducted in-theater); or to the AF/SG Office of Research Oversight and Compliance for IACUC protocols and for greater than minimal risk human studies.

The time needed for study approval by the IRB or IACUC can vary depending on the complexity of the study design, specific organizational policies, and/or if a 2nd Level Service Headquarters review and approval is required. As a result the 59 MDW/ST highly encourages investigators to initiate this process as soon as possible. The ST staff is committed to providing assistance at every step of the research review process noted above.

Literature Search

A review of literature provides assurance to protocol or funding reviewers the study is new and innovative. The literature review also provides information on similar studies and methods to improve design of the research study. A literature review should encompass the previous three years prior to study submittal and provide from 5 to 10 relevant, scholarly citations.

- Support – The 59 MDW Medical Library can provide articles not available on the AF website. For assistance send an email to 59.MDW.Medical.Library@us.af.mil.
- A request for additional guidance on, and assistance with, literature reviews can be submitted to the ST Office.

Protocol Narrative

It is important to first develop an outline that includes an overall research question/hypothesis and 2-3 specific aims. This demonstrates to the reviewer how you are going to answer your research question or test your hypothesis. It is critical your specific aims are focused and address gaps in the literature. The background section should reflect your commanding knowledge of the topic and existing gaps in the research. A short paragraph on the military relevance of your research should be anticipated and prepared. It is good practice to keep a copy of the current research thrust areas when developing the 150-200 word narrative on military relevance. The ST Office employs 3 research scientists that regularly provide assistance in preparing the study design and data analysis sections of the research protocol. Additionally, our research scientists are available to review your human subject or animal research protocol before submission to the CRD. Please note that Food and Drug Administration (FDA) approval is needed for all investigative new drug (IND)/investigative device exemption (IDE) investigations. The ST Office has an on-staff FDA expert for assistance with research protocols that seek to investigate a new drug or device. Coordination with other service offices may be required (e.g., FDA controlled protocols, clinical investigations, clinical trials, etc.). The ST FDA expert will assist with any necessary coordination.
Training Required To Conduct Research

All research investigators seeking to conduct research involving human subjects are required to complete Collaborative Institutional Training Initiative (CITI) training before submitting their research protocol to the 59 MDW IRB. This training can be easily completed at any work station where you are able to login to your “.mil” account. For additional details, please refer to Appendix D.

All research investigators seeking to conduct live animal research or training are required to complete American Association for Laboratory Animal Science Learning Library Training (AALAS). For additional details, please refer to Appendix D.

Preliminary Review

All human research protocols are submitted to the Office of Research Protocol Support 4 to 6 weeks prior to the next scheduled monthly IRB meeting. During the time before the meeting, the investigator is able to meet with IRB personnel to address any questions or concerns before the monthly IRB meeting. It is at this monthly meeting where protocols are reviewed; approved, conditionally approved pending changes, tabled/deferred, or disapproved. In the case of a deferral or disapproval we ask that the investigator work with the CRD staff to address IRB concerns. As always, the ST staff is available to assist with the revision preparation.

All animal research protocols are submitted to the IACUC office 5 weeks and 1 day prior to the next scheduled monthly IACUC meeting. Within the first 2 weeks following submission, the investigator is able to meet with CRD staff for an optional pre-review to address any questions or concerns before the monthly IACUC meeting. It is at the monthly IACUC meeting where the following determinations are made: approval; required modifications to secure approval, or approval is withheld. In the case where an approval is not immediately granted, the ST staff is available to assist with the revision preparation.

What to Expect at the IRB Meeting?

A principal investigator or representative is invited to the IRB meeting to provide a general overview of their research study to the IRB committee and answer any questions or concerns. This is optional for the PI, but highly encouraged. The board then reviews and votes.

What Happens If I Receive a Conditional Approval Letter?

A study is conditionally approved when specific IRB-directed stipulations and/or changes are required for the protocol. The conditional approval letter is required for a funding award depending on the type of funding requested. The revisions suggested in the IRB conditional approval letter must be completed within 30 days or the study may be administratively withdrawn. IRB-requested changes must be completed in track-change, highlighted or colored text; and returned to the Office of Research Protocol Support for further review by a Designated IRB Reviewer or for review through a fully convened IRB meeting.

The Final Protocol Approval Letter

An IRB final approval letter is granted if the study is approved without changes; and all IRB-directed stipulations and/or changes have been made and submitted to the IRB. Greater than minimal risk studies must go to second-level review prior to approval.

What Are IRB Progress Reports?

All researchers are required to provide Annual/Continuing Reviews; and a Final Report upon completion of the study. The final IRB approval letter will note the expiration date of the study and the date your annual report is due. Please note, failure to complete and submit required reports may result in suspension or termination of your study. Based on the risk level of your study, you may be asked to provide reports more frequently than annually. Refer to the Reporting section for additional information.
What to Expect at the IACUC Meeting?

A principal investigator or representative is invited to the IACUC meeting to provide a general overview of their research study to the IACUC and answer any questions or concerns. This is optional for investigators, but highly encouraged. The board then reviews and votes.

What Happens If I Receive a Letter Requiring Modifications to Secure Approval?

A study requiring modifications to secure approval cannot proceed until the modifications are made and reviewed, either by designated reviewers or by full committee review. The modifications must be completed within 90 days in most cases, or the study may be administratively withdrawn. The IACUC-requested changes must be completed in track-change, highlighted or colored text; and returned to the IACUC Office of Research Protocol Support for further review by a Designated Reviewer or for review through a fully convened IACUC.

The Final Protocol Approval Letter

A final approval letter is granted if the study was approved without changes or all IACUC-directed modifications have been made and submitted to the IACUC. Certain protocols must be submitted to SGE-C for review and approval prior to implementation (DoDI 3216.01). Protocols are approved for three (3) years contingent upon annual review, after which time, they must be revised and re-submitted for de novo review.

What Are IACUC Progress Reports?

All researchers are required to provide Annual/Continuing Reviews; and a Final Report upon completion of the study. The Final IACUC Approval Letter will note the expiration date of the study and the annual report due date. The IACUC may require more frequent reports for certain studies (e.g., following model development animals). Please note, failure to complete and submit required reports may result in suspension or termination of your study. Refer to the Reporting section for additional information.

Where Do I Find Funding For My Study?

The ST Office regularly provides funding source assistance. If you have identified a funding source, the ST employs experts who can assist in preparing budgets, identifying contract labor vehicles for study staffing, and developing the logistics for procuring supplies and/or equipment. For studies that seek extramural (e.g., outside the 59 MDW) collaboration, the ST Office is the POC. ST has expertise in coordination of Cooperative Research and Development Agreements (CRADAs) and other research agreements, and interfaces with the AFMSA Office of Research and Technology Applications (ORTA). For additional funding opportunity information refer to the Reporting section.

59 MDW HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

The 59 MDW Human Research Protection Program (HRPP) exists to protect the rights and welfare of persons who voluntarily participate in research studies conducted by 59 MDW researchers. The conduct of research is deeply connected to the 59 MDW, the Air Force's premier healthcare, medical education and research, and readiness Wing. The 59 MDW is committed to the highest standards of research integrity.

While the protection of human participants is shared among the 59 MDW organizations, each staff member has a role and individual responsibility in the 59 MDW HRPP, the responsibility for the HRPP resides with the 59 MDW Commander. The 59 MDW Commander is the Institutional Officer (IO) recognized by the Air Force Surgeon General's Research Oversight and Compliance Division (AFMSA/SGE-C). Day-to-day IO responsibilities for the protection of human research subjects are delegated to the Authorized Institutional Official (AIO), currently the 59 MDW Chief Scientist and Chief Medical Officer (CMO).
59 MDW Scientific Advisory Committee (SAC)

The Scientific Advisory Committee operates to align priorities and state-of-the-art research at the 59 MDW which integrates with Air Force Medical Service (AFMS) and Joint Program Committees’ (JPCs) requirements, as well as SAMMC and SAMHS research. This is essential in order to provide Air Force (AF) investigators with the structure and support to conduct, translate, and disseminate clinically-based research. An advisory body provides leadership to both academic and research endeavors in order to align and advise on competing priorities. The SAC has the following subcommittee 59 MDW HRPP Steering Committee, and the Scientific Ethics Committee.

59 MDW HRPP Steering Committee

The HRPP Steering Committee is comprised of 59 MDW institutional components, DoD, and non-DoD affiliated institutional representatives (e.g., contractors). The Committee is charged with establishing procedures to fully integrate the 59 MDW HRPP institution-wide and to ensure the HRPP is maintained in accordance with institutional, federal, State, and local laws, regulations, and guidelines. The Steering Committee reports to the Scientific Advisory Committee (SAC).

59 MDW Scientific Ethics Committee (SES)

The Scientific Ethics Subcommittee (SES) acts as the Conflict of Interest (COI) Committee for the 59 MDW. The committee reviews financial disclosures from research personnel and determines if any disclosures present a significant conflict of interest. The SES manages conflicts of interests by drafting COI Management Plans which require approval by the 59 MDW IRB and AIO. The SES is a sub-committee of the SAC.

59 MDW Institutional Review Board (IRB)

The mission of the 59 MDW Institutional Review Board (IRB) is to protect the rights and welfare of human research subjects recruited to participate in non-exempt human research protocols at the 59 MDW and other DoD or non-DoD sites in which the 59 MDW IRB is the IRB of Record. The 59 MDW IRB currently makes official determinations regarding whether activities are not research involving human subjects, exempt research involving human subjects, or research involving human subjects requiring IRB approval prior to initiation (32 CFR 219 and DoDI 3216.02_AFI 40-402).

Helpful IRB Processing Tips

- Engage the Office of Research Protocol Support early in the process to review a checklist of documents needed for the protocol type.
- Allow enough time for consistency and completeness.
- Ensure protocol and ICD information matches exactly (e.g., risks/benefits, study procedures/methods). Document version control is extremely important.
- Though the IRB Committee is diverse and well-educated both formally and informally, there is the potential they are not familiar with the particular research being reviewed. Avoid the use of technical or field-specific jargon and acronyms whenever possible. If use of jargon or acronyms is necessary clearly define each, the first time used.
- Describe in detail the experimental design including all materials and all procedures to be performed. Anticipated research related procedures should be clearly and sequentially described.
- Explain how the risks are outweighed by the benefits or the risks are reasonable in relation to the benefits; and justify the benefits statement.
- Describe why you chose the sample size proposed. Sample size may be justified by the need to assess variability in the sample or to look for large effects. A power analysis can be determined after meeting with the ST statistician.
• Justify design regarding what conclusions will be drawn (e.g., feasibility, adverse effects, etc.).
• Describe what measures will be taken to prevent, or to minimize the effects of hazards, discomforts, or inconveniences to participants.
• Provide the specifics regarding who will be monitoring the participants, data collection, frequency of monitoring, and provide a clear description of the safety assurances.
• PIs are required to maintain a regulatory file/binder of all approved documents and correspondence from IRB and other regulatory agencies

**Principal Investigators and Research Staff Responsibilities**

Principal Investigators and research staff primary responsibility is to safeguard the rights and welfare of research subjects; and ensure subjects’ rights and welfare take precedence over the goals and requirements of society and the research. Any questions related to this responsibility or the policies and procedures for protection of human subjects, should be directed to the Clinical Research Administrator or the 59 MDW IRB Chair. To obtain additional information regarding the HRPP, investigators and research staff can visit: [https://kx.afms.mil/kj/kx8/59MDWScienceAndTechnology/Pages/home.aspx](https://kx.afms.mil/kj/kx8/59MDWScienceAndTechnology/Pages/home.aspx).

**Financial Conflict of Interest (FCOI)**

All researchers, to include research staff with a conflict of interest must submit a *Financial Conflict of Interest Disclosure Form* to the Institution. Researchers must also submit the same disclosure form upon any changes to their financial circumstances that may create a research-related conflict. The researcher will send this form by encrypted email to 59MDW.ST.HRPP@us.af.mil for review and routing to the SES, if necessary. All researchers with a significant conflict of interest will require a COI Management Plan for approval by the 59 MDW IRB and AIO. The IRB will review all institutional approved COI Management Plans. No protocol will be approved by the 59 MDW IRB until a COI Management plan is approved by the AIO, if necessary.

**FDA-Required Training for the PI**


**Quality Assurance/Quality Improvement**

Quality assurance (QA) and quality improvement (QI) is the responsibility of the Research Compliance Office. The Research Compliance Officer monitors research involving the use of human subjects approved by the IRB. Activities may include direct audits of study records at the study site, contact with the research sponsor and/or monitoring organizations, contact with other IRBs, interviews with research staff and research participants, and/or review of records within the IRB.

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

Research involving animals has extensive requirements that must be met under the requirements of the 59 MDW Institutional Animal Care and Use Committee (IACUC). The Air Force Medical Support Agency Division of Research Oversight & Compliance Animal Research Informational Resources may be contacted for additional requirements. This guide covers the care and use of laboratory animals in DoD programs.

All investigators are required to keep protocol binders current with correspondence from the Office of Research Protocol Support, CVs, AALAS training certifications, data collection sheets.
CRD QUALITY ASSURANCE/QUALITY IMPROVEMENT

Quality assurance (QA) and quality improvement (QI) is the responsibility of the Research Compliance Office. The Research Compliance Office ensures quality assurance (QA) and quality improvement (QI). They conduct post-approval monitoring research involving the use of animals which may include: direct audits of study records at the study site; contact with the principal investigator; veterinary and/or IACUC observation of animal procedures; interviews with research staff; and/or review of records within the IACUC Office of Research Protocol Support.

FUNDING

Research funding can be attained using many different vehicles. Most often funding is received by the 59 MDW via a Funding Authorization Document (FAD). The ST Office coordinates with the 59 MDW Resource Management Office (RMO) to ensure the FAD is assigned to the appropriate project. Once established funding is categorized into Element of Expense Identification Codes (EEIC). Examples of research project categories are: travel, supplies, equipment, contracting, and pharmacy. The ST Office will assist the PI in tracking budget execution and providing financial reports to the applicable funding agency. A breakout of funding types received is listed below:

RDT&E

Research, Development, Test, and Evaluation (RDT&E) requirements funding is designed for more advanced or complex research projects require multi-year funding and is provided by DHP. A RDT&E funding proposal should include contract labor, TDY expenses, supplies, and equipment. Depending on the specific organization RDT&E funding is available for multi-year use.

<table>
<thead>
<tr>
<th>Types of DHP RDT&amp;E Funding</th>
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<tbody>
<tr>
<td>6.1 Basic Research</td>
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<tr>
<td>Attaining greater knowledge and understanding of fundamental</td>
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<tr>
<td>principles of science and medicine.</td>
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<tr>
<td>6.2 Applied Biomedical Research Technology</td>
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<tr>
<td>Refinement of concepts and ideas into potential solutions with</td>
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<tr>
<td>a view toward evaluating technical feasibility.</td>
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<td>6.3 Medical Technology Development</td>
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<tr>
<td>Development of candidate solutions and components of early</td>
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<tr>
<td>prototype systems for test and evaluation, including support</td>
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<tr>
<td>of early stage clinical trials.</td>
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<tr>
<td>6.4 Advanced Component Development</td>
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<tr>
<td>Clinical trials for FDA licensed products and accelerated</td>
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<tr>
<td>transition of FDA regulated and non-regulated products and</td>
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<tr>
<td>medical practice guidelines to operational users through</td>
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<tr>
<td>clinical and field validation studies.</td>
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<td>6.5 Medical Systems Development</td>
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<tr>
<td>Development of demonstration of medical commodities prior</td>
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<tr>
<td>to initial full-rate production and fielding, including</td>
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<tr>
<td>initial operational test and evaluation and clinical trials.</td>
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<tr>
<td>6.6 Management Support</td>
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<tr>
<td>Infrastructure and civilian salary support.</td>
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<tr>
<td>6.7 Medical Systems Sustainment Activities</td>
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<tr>
<td>Pre-planned product improvement of fielded medical products</td>
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<tr>
<td>and evaluation of the effectiveness of fielded products,</td>
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<tr>
<td>therapies, treatments, or medical guidelines.</td>
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</table>

O&M

Operation and Maintenance (O&M) appropriations are used to finance “expenses” not related to military personnel or RDT&E. O&M appropriations are available for obligation for one fiscal year. These proposals are announced in the 3rd or 4th Quarter and have 4th Quarter deadlines. These clinical studies promote Graduate Health Sciences Education (GHSE)/Graduate Medical Education (GME) involvement and focus on clinical studies.

The above descriptions require interpretation when applying them to DHP funding. For example, under DHP guidelines, it is permissible to use O&M funding for clinical studies of short duration (1 year). O&M funds can also be
used for an early operational assessment to determine the maturity of a technology. O&M funding can also be used for feasibility studies to determine if there are technologies that can be used to address certain problems. SG5I uses O&M funds for the Clinical Investigation Program (CIP) Intramural Call for Proposals and to award funds for proposals submitted to the AFMSA Broad Agency Announcement (BAA). R&D funds are typically used for multi-year programs developing novel capabilities or research that will add to the current body of knowledge.

**Procurement**

Procurement—also referred to as “Other Procurement/OP”—appropriations are used to finance investment items and to cover all costs necessary to deliver a useful end item intended for operational use or inventory. Items classified as investments, and financed with Procurement appropriations include those whose system unit cost exceeds $250K. It is unusual for research projects to acquire materials for a project using these type of funds. Funding for large equipment required for a research study is usually written as part of the budget in the initial funding proposal.

**59 MDW Resource Management Office (RMO)**

59th MDW Resource Management Office (RMO) is able to receive R&D, O&M and Procurement funds. If modernization initiatives or projects are awarded, RMO will determine the type of funds appropriate for the initiative or project. The RMO office has Resource Advisors specifically trained with experience in handling these different types of funds. It is important to work with the RMO to clarify verbiage for execution of these funds. RMO will work with the ST Office to move funds to another organization if the initiative or project has a requirement at another facility.

RMO is also able to receive funds provided as gifts and funds use for travel in accordance with MDWI 51-601, individuals conducting research must disclose gifts, including travel, having an aggregate market value of $20 or more per source per occasion, provided that the aggregate market value of individual gifts received from any one person will not exceed $50 in a calendar year. This exception does not apply to gifts of cash or investment interests (e.g., stocks, bonds, certificates of deposit).

**FUNDING OPPORTUNITIES**

Funding awards are categorized as intramural or extramural. Intramural awards are derived from announcements for research funding have specific requirements. The announcements are available throughout the year. More information on the latest research funding opportunities can be found by contacting the ST Office and at:


**Intramural Awards**

**CRD (CIP) Baseline GME/GHSE Intramural Funding**

- Program 8 (O&M) – One-year money to support resident/fellow research. Can be used to purchase supplies and in some cases equipment. Cannot be used to purchase manpower or travel.

**AFMSA/SG5 Intramural Award**

- Program 8 (O&M) – Award has less than 1 year execution and funding limits up to $200K on average.
- Program 6 (DHP RDT&E) – AFMSA DHP RDT&E funds are disbursed to the 59 MDW and 711th Human Performance Wing (711 HPW)-USAFSAM by AFMSA/SG5 each year. 59 MDW/ST releases intramural proposal calls to competitively award funds for research executed for 2 years up to 3 years. Funding limits vary; however, awards are generally up to $1 million per submission depending on several factors to include availability of funds and research alignment to prioritized capability gaps based on AFMS and MAJCOM mission needs. The funding is
administered and managed locally; proposals are independently reviewed and scored; and results presented to senior wing leadership.

**Congressionally Directed Medical Research Program (CDMRP)**

- The CDMRP is the largest source of intramural funds and is available for civilian and military researchers. External collaborations from research institutions are encouraged.

- Program 6 (DHP RDT&E) can be executed for up to 2 years. Projects can be up to several million dollars.

**UTHSCSA Institute for Integration of Medicine and Science (IIMS)**

- The University of Texas Health Science Center San Antonio (UTHSCSA) IIMS award focuses on translational research projects for up to 1 year execution. Funding is through the National Institute of Health (NIH) Clinical and Translational Science Awards (CTSA) program and intramural research may engage with other CTSA consortia.

**Private Sector**

- Industry funded research using nonprofit agencies is usually limited to scope and subjects.

**Extramural Awards**

**Congressionally Directed Medical Research Program (CDMRP)**

- This award is open to academia, industry and non-profit institution; and intramural collaborations are encouraged. The execution period is up to 2 years and up to several million dollars per award. This is also Program 6 funding (DHP RDT&E).

**National Institute for Health (NIH) Multi-Institutional Announcement(s)**

- This type of study may include DoD facility/collaborators.

**U.S. Army Medical Research and Materiel Command’s (UAMRMC) Broad Agency Announcement (BAA)**

- The UAMRMC BAA announcement is continuously open. The purpose of the announcement is to enrich both military and civilian medical practice and knowledge. The BAA considers solicitations from national, international, for-profit, non-profit, public, and private organizations.

**Tri-Service Nursing Research Program (TSNRP)**

- This award supports rigorous scientific research studies and evidence-based practice projects in the field of military nursing. It is the only program that focuses exclusively on research in this field.

TSNRP offers awards for nurses at all stages of their careers. Grant applicants may be: Active duty, Reserve or retired; military nurses from the United States Army, Navy or Air Force; or National Guard Nurse Corps Officers. For more information visit [https://www.usuhs.edu/tsnrp/mission](https://www.usuhs.edu/tsnrp/mission).

- Research awards include:
  - Graduate Research Award
  - Novice Investigator Award
  - Exploratory Research Award
  - Career Development Award
  - Investigator-Initiated Award
• The evidence-based practice awards are the:
  • Graduate Evidence-Based Practice Award
  • Conceptual Guideline Development Evidence-Based Practice Award
  • Implementation of Innovation Evidence-Based Practice Award

Other

• www.grants.gov lists many current calls for proposals from federal agencies.

RESEARCH PROPOSAL

All funding applications require a research proposal; in some instances an IRB approved research proposal. The award announcement identifies specific guidelines for submission. All submissions will vary in length, format and information needed. Follow the instructions carefully for a complete submission and to ensure grantor review.

The Pre-Proposal Submission

The pre-proposal usually is a condensed version of a full proposal for the funding reviewers to select research projects that best fit identified gaps. Documents to be included in the submission vary depending upon the announcement. A white paper is usually required and will condense the background, military relevance, hypothesis/research question, aims, methods, references, and deliverables of the study. The cost proposal needs to address funding needed for personnel, equipment, supplies, and travel. In addition a QUAD chart is typically required. A QUAD chart is a single PowerPoint slide is divided into 4 sections. These sections vary, but usually include title, investigator, background, military relevance, overall budget, picture, and deliverables. The ST Office can provide a QUAD chart template.

Selection for Full Proposal

Pre-proposals are competitively selected to go through the full proposal process. A full proposal should carefully follow the guidelines identified in the program announcement. Items required may include the following (please see the ST Research Cell for the current template):

a. Abstract
b. Background
c. Military Relevance
d. Technical Program Summary/Methods
e. References
f. Milestones/Deliverables
g. Facilities/Equipment/Experience
h. Subcontracts
i. Cost proposal (see below budget)
j. Biosketch of Investigator and Co-Investigator
k. Letter of Support
l. Quad Chart

Budget Development for Research Proposal

**Labor:** The first step is to determine the service contract labor standards. A Performance Work Statement (PWS) describes the type of work required. Also required is the Contract Data Requirements List (CDRL), this includes the deliverables that will be submitted to the funding agency (e.g. final reports, interim reports, data packages, etc.) from the contractor. The ST Budget Analyst will assist with finalizing the package and coordinating the funding with a contracting route. If the acquisition route is using a contracting office, the request will be advertised to the
contractors for 14 days, at which time, each contractor who wants to bid will submit a proposal. A grant or cooperative agreement requires a Statement of Work (SOW). The ST Office can provide an example.

**Common Research Labor Categories**

- Research Nurse Coordinator
- Research Coordinator
- Research Assistant
- Clinical Research Scientist
- Epidemiologist
- Statistician
- Veterinary/Surgical Technician
- Project Manager

**Supplies and Equipment (Medical):** A list of research project supplies and equipment should be drafted by using vendor quotes. Overhead charges may apply; the ST Office is able to assist with the totals for each organization. Once funding has been received, a Project Funds Management Record (PFMR) letter will allow access for a research member to order supplies from the established MEDLOG account through the Defense Medical Logistics Supply System (DMLSS). The estimated time for an account to be established is 4-6 weeks. Once the account is established, supplies and equipment (up to $3K) may be ordered. If an item exceeds $3K, the item will be purchased through contracting. A Form-9 and Sole Source Justification may be required for the procurement action/purchase. The ST Office will assist with the required documents.

**Equipment (non-Medical):** There are three methods for ordering non-medical equipment: Government credit card, Form-9 and contract.

**Travel (TDY):** ST will provide the travel cost estimate (investigator must provide the date of the conference/training, location, number of people traveling, conference fees). **NOTE:** Travel must be completed within the same years as the funding for O&M funded projects. RDT&E funded projects allow for project related travel to occur during the length of the project.

Each funding announcement contains specific travel funding requirements. If you have any questions, the ST Research Cell can provide a template for travel.

**Facility Fee:** Facilities such as the U.S. Army Institute for Surgical Research (USAISR), Navy Medical Research Unit (NAMRU) and universities have additional overhead or laboratory fees that also must be figured into the project total costs. The ST Office can assist with adding these fees into the research budget.

**REPORTS AND REVIEWS**

Technical and financial reports are required quarterly, annually and research study closure. For AFMS funded projects, the ST Office will assist with the quarterly report and other requested reports. For DMRDP funded projects, the Joint Program Committee representative will contact the PI or external collaborator directly and the PI is to coordinate with the assigned ST Project Manager. The DMRDP will normally send the format along with report requirements and instructions. There is also a semi-annual Research Program Review conducted by the 59 MDW Chief Scientist to assess scientific and programmatic progress prior to the AFMS Research and Technology Advisory Board (RTAB) that examines scientific merit. Following the RTAB review, a Program Management Review (PMR) is held by AFMSA/SG5, then a programmatic review is conducted with AF/SG 3/5, AFMSA/SG5, 59MDW, 711HPW-USAFSAM and MAJCOM Command Surgeon representatives. These reviews provide an in-depth overview of the Wing and AFMS research portfolio to baseline programs and assess progress on addressing AFMS and MAJCOM capability gaps. These reviews are critical in preparing reviews to the Defense Health Agency (DHA) Research and Development Directorate and the Defense Medical Research and Development Program. ST will coordinate the format and suspense requirements with the PI. A kick-off meeting will be held with ST staff, the PI and research team prior to project initiation to introduce reporting requirements.
Quarterly Reports

Quarterly reports are required once a program/initiative is started.

AFMSA Quarterly Progress Update Reports (QPUR):

The QPUR is prepared and delivered in the format of a PowerPoint slide set, drafted by Principal Investigators and the ST Program Managers (PMs); then submitted to AFMSA/SG5. The QPUR is to update the funding organization on current status of cost, schedule and performance.

DMRDP/JPC Technical Reporting Requirements:

The majority of JPC funded studies have an extramural collaborator, who is identified to conduct the approved study. The extramural collaborator or recipient is awarded a cooperative agreement by the U.S. Army Medical Research and Material Command (USAMRMC). These agreement awards have special terms and conditions clauses to include the technical reporting requirements.

SG Intramural Quarterly Reporting Requirements:

Quarterly reports are required to update the funding agency on status of the project, budget and research presentations. At the initial notification of award, the organization will provide a template for the quarterly report. The ST Office is able to assist the GME or investigator with these reports.

Clinical Investigations Program (CIP) Quarterly Updates:

The 59 MDW CIP collates data on 59MDW medical research writings and oral presentations prepared by personnel assigned to the Wing. This information is collated each quarter and the CRD submits the report to the AFMSA/SG5 Program Manager. The report includes program accomplishments and significant events, significant studies, presentations, and publications. GME/GHSE will be contacted by CRD staff if information is required for the AFMSA/SG5 quarterly report. Additionally, these research writings and presentations are uploaded to DTIC on a regular basis. Refer to MDWI 41-108 for more information.

Other reports: Annual and Close-Out/End of Project Reports

Annual Protocol Reports:

These are IRB and IACUC required documents. An Annual Protocol report template is provided by the Office of Research Protocol Support or the IACUC Office of Research Protocol Support. The purpose of the report is to summarize the research completed that year as requested in each section of the template.

Protocol Final Reports:

These are IRB and IACUC required documents. A protocol final report is required by the IRB and IACUC. The purpose of the report is to summarize the entire research performed over the duration of the study to permanently close the work.

Project Final Reports – Technical and Programmatic:

A report is required to be submitted in Defense Technical Information Center (DTIC). The ST Office will assist investigators in the preparation of this report. All documentation on DTIC requires a Public Affairs determination for
approval. Contact the CRD for 59 MDW Form 3039 requirements to obtain Public Affairs approval. CRD will submit your cleared report into DTIC. Refer to MDWI 41-108 for more information.

**FOOD AND DRUG ADMINISTRATION (FDA)**

The FDA is responsible for implementing the laws and articulating regulations and guidelines for clinical studies involving regulated medical products. FDA will be responsible for receiving Investigational New Drug applications (IND) and Investigational Device Exemptions (IDE) reviewing them to assure that the requirements are met. At the appropriate time, the FDA is also responsible for receiving applications for marketing approval. Depending on the medical product involved, these marketing applications can include New Drug Applications (NDAs) including biologics, and medical device clearance Pre-Market Notification (510k), or approval Pre-Market Approval (PMA) requests.

FDA Regulated Medical Products of concern to the Air Force:

1. **Drugs, including therapeutics [biologics previously regulated by the Center for Biologics Evaluation and Research (CBER)]**
   - For practical purposes in defining a drug, a drug is a molecular entity that provides its intended effect(s) by being metabolized in/on the body.

2. **Medical Devices and In-Vitro Diagnostics**
   - For practical purposes in defining a device, a device provides its intended effect(s) mechanically or in other ways and is NOT metabolized in/on the body.

3. **Biologics**
   - Biological products include viruses, therapeutic sera, toxins and antitoxins, vaccines, blood, blood components or derivatives, allergenic products, and analogous products used for treating disease.

4. **Combination Medical Products**
   - A product comprised of two or more regulated components, such as a medical device and drug.
   - For combination medical products, the primary mode of action tends to dictate how FDA handles the combo product from a regulatory perspective. For example, a syringe loaded with a drug, such as an antibiotic is considered as having a primary mode of action as a drug. A drug coated stent is considered as having a primary mode of action as a device; as the main intent is to mechanically support the vessel where the stent is placed.

FDA regulates medical products differently based on how the medical product fits within the definitions above, in particular the intended/indications for use. All projects involving FDA issues should contact the subject matter expert in the ST Research Cell.

**RESEARCH AGREEMENTS/TECHNOLOGY TRANSFER (ORTA REVIEW)**

There are different types of agreements that may be required to conduct research:

**Cooperative Research and Development Agreement (CRADA)** is a written agreement between a federal research organization and one or more federal or non-federal parties (collaborators) to work together as partners on a research project of mutual interest. Refer to Appendix E.

- **Material Transfer Agreement (MTA)** is a contract between two organizations for the transfer research materials to be used for research purposes of the intended recipient.
• **Data Use Agreement (DUA)** is a contractual document used for the transfer of data that has been developed by nonprofit, government or private industry, where the data is nonpublic or is otherwise subject to some restrictions on its use.

• **Non-Disclosure Agreement (NDA)/Confidential Disclosure Agreement (CDA)/Proprietary Information Agreement (PIA)** is a contract by which information covered by the agreement is not disclosed and agreed to by both parties.

• **Institutional Agreement for IRB Review (IAIR)** (also known as an Institutional IRB Agreement) is a written agreement allowing reliance upon another institution's IRB. The IAIR defines the responsibilities and authorities of each institution in complying with the terms of each institution's Federal assurance and DoDI 3216.02. The scope may be for a single identified project, a specified group of studies, or for all research conducted by the institution relying on the external IRB.

• **Individual Investigator Agreement (IIA)** is an agreement between an institution and a single investigator to cover the investigator under the institution’s Federal assurance. Scope of the agreement can be a single identified project, a specified group of studies, or for all research conducted by the investigator at the respective institution providing the Federal assurance coverage.

• **Memorandum of Understanding (MOU)** is a contract to set up a research or educational partnership between two or more parties.

• **Interagency Cooperation Contract (ICC)** is a written agreement under which goods or services are provided between agencies of the State of Texas.

• **Sub-Award Agreement (SAA)** is an agreement with a third-party organization performing a portion of a funded educational institution research project or program.

• **Collaborative Research Agreement (CRA)** is a contract between an educational institution and one or more organizations that are cooperating in the conduct of a research program.

• **Teaming Agreement (TA)** is a binding agreement in response to a competitive request for proposal (RFP) between one or more organizations that are joining together to propose a new cooperative research project to a prime sponsor (e.g., federal government agency).

**What Is Included in The Most Common Research Agreement?**

A CRADA is the most common agreement required to conduct research. The written agreement typically includes general provisions in a standardized format that provides the legal framework for the agreement. A Statement of Work (SOW) describing the objectives, tasks and deliverables of the collaborative project is included. The following may be included in the CRADA:

- Personnel
- Services
- Facilities
- Equipment
- Other resources

**Are Proprietary Ideas Protected?**

Yes. At the conclusion of the cooperative effort, the results may often be considered proprietary. All parties agree to keep the research results confidential to the extent permitted by the law until they are published in scientific literature or presented at a public forum. The private industry cooperator can retain patent and intellectual property rights or retain an exclusive license to a patent. The government has the right to use any information; however, must respect the proprietary rights of the cooperator. In addition, any other government agency may use the information emerging from a CRADA effort but it must also protect the cooperator’s proprietary rights. The proprietary right protection gives added incentive to the cooperator for transferring the technology or research development through marketing and commercialization efforts.
RESEARCH CONFERENCES

Military Health System Research Symposium

The Military Health System Research Symposium (MHSRS) is the tri-service symposium which incorporates ATACCC, AFMS, and Navy Medicine Research Conference. This symposium is co-sponsored by the Defense Medical Research and Development Program and Joint Program Committee 6, Combat Casualty Care Research Program. It is the premier DoD scientific meeting to address the unique medical needs of the warfighter and a collaborative environment for military medical care providers with deployment experience, DoD scientists, academia, and the industry. Presenters and attendees discuss and present the advancements of research and healthcare development in areas of Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, and Military Infectious Disease Research Programs. The aim is to optimize care for members of the Uniformed Services in operational settings. The MHSRS is held annually in August, investigators receiving AFMS funds are required to submit an abstract for presentation. The ST Office is available for assistance with abstract submissions. Additional MHSRS information is available at http://mhsrs.com/.

Clinical Investigation Research Symposium

The Clinical Investigations Research Symposium (CIRS) is a biannual symposium available to all GME students. While residents have priority for attendance, the CIRS is open to all health care professionals. This venue provides an overview of local research activities—presentations and posters—and offers basic and advanced sessions on protocol and proposal preparation.

SAMHS and Universities Research Forum (SURF)

SURF is an annual local symposium and collaboration between University of Texas-San Antonio, University of Texas Health Science Center at San Antonio and the San Antonio Military Health System. This venue provides an overview of both collaborative research efforts as well is institutional projects. This is an excellent forum for networking with regional experts with a variety of clinical and non-clinical backgrounds.

SCIENCE AND TECHNOLOGY RESEARCH SUPPORT

Orientation: When a research protocol is approved and prior to funding being released, ST staff will conduct a meeting with each PI.

IACUC/IRB: The ST Office can assist with protocol development prior to submitting for a funding opportunity. All funding requires an approved IRB/IACUC protocol.

Performance Work Statement (PWS): A PWS is required to obtain personnel for a funded research study. An example PWS is available in the ST Office.

Statement of Work (SOW): Required for grant/cooperative agreements (assistance to academia or industry) or a contract that the government receives a product.

Supplies and Equipment: Complete a cost estimate including a list of supplies and equipment with vendor quotes, sources, total costs (including shipping and maintenance plans if applicable when purchasing equipment). A surcharge may apply when ordering supplies and equipment. The amount varies depending upon which organization submits the order.

Information Management/Information Technology (IM/IT): A cost estimate including a list of all required computer hardware and software with vendor quotes, sources, total costs (including shipping and license fees), and any plans (if applicable for equipment) will be submitted for purchase.
• Reports: Technical and financial reports are required quarterly and annually. ST is available to assist with templates and completion of the reports: 59 MDW/ST funded projects – ST Office submits quarterly reports to AFMSA/SG5 in coordination with the PI, and requires semi-annual and annual reports from the PI.

• DMRDP funded projects: PI or Foundation submits the quarterly reports.

• Additional reviews and/or approvals may be required if the research involves using or developing IT systems or software applications not currently approved by Defense Information Systems Agency of Defense Health Agency, please coordinate with the your IT Department and HIPAA Office.

Budget Management: When crafting a research proposal for funding, please consult with the ST staff for all costs related to your project to ensure the most accurate cost estimates for proper funding. Labor, Equipment, Supplies, and Travel should all be incorporated in the research budget.

Contracting: Investigators need contracts if labor or equipment is to be purchased. The ST staff has expertise in assisting the PI with drafting the appropriate documents and providing follow up on items requested.

PROGRAM MANAGEMENT REVIEWS (PMRs):

PMRs provide scientific and program analysis to SG5 and MAJCOM Command Surgeons. Program status is presented twice a year at the 59 MDW Research Portfolio Review, AFMS scientific merit and programmatic (cost, schedule, performance) reviews with SG5, 59 MDW, 711 HPW and MAJCOM Command Surgeon representatives (AFMSA SG5 Semi-annual Reviews, AFMS Research and Technology Advisory Board and AFMS Medical Research and Acquisition Working Group). The ST Office assigned Project Manager will assist the principal investigator with documentation needed for the PMR. The Principal Investigator presents the documents to the ST Office and answers questions related to the research study. A pre-PMR is optional for the ST and SGSI offices to gather correct information for the semiannual reviews. Appendix C provides an overview of the AFMS Corporate Process and Wings Role in Research Execution.
ST CONTACT INFORMATION

Chief Scientist / ST Main Office  (210) 292-2097 (DSN 554)
ST Deputy Chief Scientist  (210) 292-6810
ST Diagnostics & Therapeutics Research Director  (210) 292-3511
ST Trauma Research Director (59 MDW)  (210) 292-5977
ST Nursing Research Director (59 MDW)  (210) 292-5931
ST Senior Program Analyst  (210) 292-3466
ST Program Manager  (210) 292-3406
ST Biostatistician  (210) 292-2971
ST Budget Coordinator  (210) 292-3452
ST FDA SME  (210) 292-2829
ST Research Scientist  (210) 292-3511
ST Scientist/Advisor  (210) 292-3513/2919
ST CRD CIP Director  (210) 292-7069
ST CRD CIP Deputy  (210) 292-5687
IRB Clinical Research Administrator  (210) 292-5203
IACUC Chair/Biostatistician  (210) 292-7295
ST CRD Laboratory Support  (210) 292-7363
ST CRD Laboratory Animal Medical Officer (LAMO)  (210) 292-2771
ST CRD Protocol Support  (210) 292-4683
ST CTR of Advanced Molecular Detection Director  (210) 292-0504
BAMC, Director, Office of the IRB  (210) 916-2598
BAMC, Protocol Coordinators  (210) 916-8936/0606/7394/4039
Joint Immunomodulation Research Director (TSRL)  (210) 5397399
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<th>Acronym</th>
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<tr>
<td>AALAS</td>
<td>American Association for Laboratory Animal Science</td>
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<td>AE</td>
<td>Adverse Event</td>
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<td>AFMS</td>
<td>Air Force Medical Service</td>
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<td>AFMSA</td>
<td>Air Force Medical Support Agency</td>
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<td>Army Knowledge Online</td>
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<td>Brooke Army Medical Center</td>
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<td>MHSRS</td>
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<td>QA/QI</td>
<td>Quality Assurance/Quality Improvement</td>
</tr>
<tr>
<td>QPUR</td>
<td>Quarterly Progress Update Report</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>RDT&amp;E</td>
<td>Research, Development, Test and Evaluation</td>
</tr>
<tr>
<td>RMO</td>
<td>Resource Management Office</td>
</tr>
<tr>
<td>RTAB</td>
<td>Research and Technology Advisory Board</td>
</tr>
<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
</tr>
<tr>
<td>SAMHS</td>
<td>San Antonio Military Health System</td>
</tr>
<tr>
<td>SAMMC</td>
<td>San Antonio Military Medical Center</td>
</tr>
<tr>
<td>SG5</td>
<td>Research and Acquisitions Directorate</td>
</tr>
<tr>
<td>SIBR</td>
<td>Small Business Innovation Research</td>
</tr>
<tr>
<td>SOW</td>
<td>Statement of Work</td>
</tr>
<tr>
<td>ST</td>
<td>Chief Scientist’s Office Science and Technology</td>
</tr>
<tr>
<td>STTR</td>
<td>Small Business Technology Transfer</td>
</tr>
<tr>
<td>TDY</td>
<td>Temporary Duty (i.e., Travel)</td>
</tr>
<tr>
<td>VTC</td>
<td>Video Teleconference</td>
</tr>
<tr>
<td>USAMMDA</td>
<td>U.S. Army Medical Materiel Development Activity</td>
</tr>
<tr>
<td>USAMRMC</td>
<td>U.S. Army Medical Research and Materiel Command</td>
</tr>
</tbody>
</table>
DEFINITIONS

**Adverse Event:** An adverse event (also referred to as an adverse experience) can be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, and does not imply any judgment about causality. An adverse event can arise with any use of the drug (e.g. off-label use, use in combination with another drug) and with any route of administration, formulation, or dose, including an overdose.

**Assent:** Agreement to participate in proposed research, given by an individual not competent to give legally valid informed consent (e.g. a child or mentally limited person). Mere failure to object may not be construed as assent.

**Assurance:** A formal, written statement submitted to a federal agency attesting that an institution will comply with applicable rules governing research with human subjects.

**Belmont Report:** The Belmont Report consists of three basic ethical principles as a basic justification for decision-making and judgments. The three principles are: 1) Respect for persons, 2) Beneficence, and 3) Justice.

**Consent:** Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject.

**Exempt Research:** Exempt research is research involving little, if any, associated risk to human subjects. This category of approval has very specific criteria and allows the research to be conducted under abbreviated and simplified rules. Six categories of research activity, as defined in the federal regulations for protecting research subjects, are inherently risk free, such as the secondary analysis of de-identified data. If research falls into one of the qualified categories, it may qualify for exemption.

**Expedited Review:** An IRB protocol review conducted by the IRB chair or a member directed by the chair without requiring a review by the full IRB committee. The protocol must be minimal risk and meet additional qualifications.

**International Conference on Harmonisation:** provides a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.

**Research Proposal:** A research proposal is a document that is written by a scientist that describes in detail a process for a proposed scientific investigation which is meant to persuade others to approve/fund their research project.

**Research Protocol:** A document that describes the objective(s), design, methodology, and statistical rationale of a research study.

**Serious Adverse Event:** An adverse event or suspected adverse reaction is considered “serious“ if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.
There are six AF Surgeon General Modernization (SG5I), Modernization Thrust Areas (MTA), overseen by the Headquarters Air Force Research and Acquisition (AF/SG 3/5) and managed by the Air Force Medical Support Agency Acquisitions (AFMSA/SG5).

<table>
<thead>
<tr>
<th>INNOVATIONS</th>
<th>FORCE HEALTH PROTECTION</th>
<th>OPERATIONAL MEDICINE</th>
<th>ENROUTE CARE</th>
<th>HUMAN PERFORMANCE</th>
<th>EXPEDITIONARY MEDICINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify, evaluate, and incubate novel concepts, new processes, or disruptive technologies</td>
<td>Prevention of recognition injury/illness &amp; the early or detection of emerging threats</td>
<td>Providing definitive patient care/treatment in-garrison</td>
<td>Continuum of care during transport of patients from point of injury to point of definitive care</td>
<td>Enhancing performance of Airmen in challenging environments</td>
<td>Improving care during contingency ops; medical countermeasures against combat/operational stressors</td>
</tr>
</tbody>
</table>
# APPENDIX B

## DMRDP Research Areas

### Defense Medical Research and Development Program (DMRDP)

Joint Program Committees, or JPCs, consists of medical and military technical experts. These experts work through coordinated efforts to translate guidance into research and development needs. The key responsibilities are to provide funding recommendations and program management support for DMRDP funded research.

<table>
<thead>
<tr>
<th>Program Areas</th>
<th>JPCs</th>
<th>Bio and Medical Informatics (JPC 1)</th>
<th>Military Infectious Diseases (JPC 2)</th>
<th>Military Operational Medicine (JPC 5)</th>
<th>Combat Casualty Care (JPC 6)</th>
<th>Radiation Health Effects (JPC 7)</th>
<th>Clinical Medicine &amp; Rehabilitation (JPC 8)</th>
</tr>
</thead>
</table>
### JPC-6 Combat Casualty Care
1. Hemorrhage and Resuscitation
2. Neurotrauma
3. Forward Surgical/Intensive Care (including advanced monitoring and lung injury)
4. Treatments for extremity trauma
5. En Route Care
6. Combat Dentistry
7. Photomedicine Research for Wounded Warriors

### JPC-7 Medical Radiological Defense
1. Radiation Biology Modeling
2. Internal Contamination/Heavy Metal Toxicity
3. Bone Marrow Program
4. Biodosimetry
5. Radiation Counter Measures
6. Radiation Combined Injury
7. Agent Defeat

### JPC-8 Clinical Medicine Rehabilitation
1. Neuromusculoskeletal Injury (Prosthetics/Amputee Care)
2. Pain Management (Acute/Chronic/Battlefield)
3. Regenerative Medicine
4. Sensory System Traumatic Injury – Vision
5. Sensory System Traumatic Injury – Hearing and Balance
6. Traumatic Brain Injury (TBI) Rehabilitation
Research Portfolio

The 59 MDW’s research lanes are specifically derived from and aligned with the 59 MDW vision, mission, and capabilities (technical base). All research is aligned to a lane, and mapped to AFMS Thrust Areas, and for research that addresses Joint medical research gaps, the Joint Program Committees of the Defense Medical Research and Development Program.

Research Lanes

- **Trauma, Resuscitation, Stabilization**
- **Therapeutics**
- **Advanced Diagnostics**
- **Medical Modeling, Simulation**
- **Clinical & Rehabilitative Medicine**
- **Clinical Investigation Program**

Lifesaving Interventions (LSI): The purpose of this study is to describe the incidence and efficacy of specific prehospital LSIs, consistent with the Tactical Combat Casualty Care paradigm, performed during the resuscitation of casualties in a combat zone.

Comprehensive Adult Extracorporeal Support Program: Extracorporeal membrane oxygenation is a technique of providing both cardiac and respiratory support oxygen to patients whose heart and lungs are so severely diseased or damaged that they can no longer serve their function. This program seeks to develop a comprehensive capability to provide extracorporeal support to adult patients in SAMMC catchment area and for combat casualties who exceed conventional transport capabilities.

The Trauma Specific Vascular Injury Shunt (TS-VIS): Limb injury from decreased blood flow can occur with blood vessel injuries, and may result in the need for limb amputation. Restoration of circulation to the limb prior to irreversible injury may result in additional injury from toxic oxygen derivatives. This study examines the newly designed TS-VIS and will test for ease of insertion, patency in the artery, and adequacy in keeping in-line flow to injured limbs.

Fractionated CO2 Laser and Burn Scar Contractures: Evaluation of Post-Treatment Scar Function and Appearance - This study aims to improve range of motion, scar compliance, and aesthetics of erythema and pigmentation, while decreasing scar thickness and minimizing side effects and the potential complications of treatment while identifying non-surgical modalities that result in expansion of the skin and reduced tension in burn contracture scars and increased pliability of burn contracture scars.

Characterization of the Proteomic Response to Hydrocodone: A Preliminary Study to Understand Physiological Responses of Opioid Abuse, Overdose, and Pain - Use of oral fluid proteomes to understand mechanism of individual predilection for drug abuse will provide new tools to reduce substance abuse (e.g. tailor drug therapy, counseling, preventive therapies).

Genetic Epidemiology of Risk-Associated Single Nucleotide Polymorphisms (SNPs) of Type 2 Diabetes (T2D) Mellitus: This study compares genetic marker incidence between T2D patients and controls within retired military/dependent populations. It also establishes frequency of heterozygosity vs. homozygosity of SNP alleles by allelic discrimination, determines statistically significant genetic markers for T2D, and assesses individual T2D risk within the active duty population.
AFMS Corporate Process

Research Technology Advisory Board (AFMS RTAB)

- Coordinates with MEFPAKs/MAJCOMs, SG5 portfolio managers
- Scientific Merit/Evaluation
- Stratification (S&T/R&D)
- Advises on S&T investment strategy

AFMS RTAB:

MRAWG:
- Review, prioritize and recommend research, development, commercialization and test activities
- Prioritize/Merge MAJCOM (1-n) lists
- Briefs JPCs on Final CBA
- Coordinates with SGROCC

HAF/SG 3/5, Medical Modernization, Aerospace Operations and Medical Operations Panels, and/or SGROCC

AFMS Group
AFMS Council

HAF SG 3/5A
AFMSA SG5

Wings*

Wings*

Execution

Materiel/ TBD
Non-Materiel/ AFMS Functional
Research/ Execution Wings

AFMSA/SG5 and MRAWG – Supports Technology Development Process, Execution and Transition Strategies

Planning
Programming
Budgeting
Execution

*59MDW and 711HPW
Execution Wing’s Roe in the Corporate Process

- Proposed Solution(s)
  - Impact
  - Cost
  - Priority
  - Initial transition
  - Planning

Validated Need

Flight Test Platform /Sensors

Individual Project

- RTAB Review of Programs for Technical merit, linkage and alignment to customer requirements and AF/SG initiatives and priorities, deconfliction, proper progress and product transition, and revising plans as needed

- Initial transition

- Planning

MRAWG Portfolio Manager

CAPABILITY DELIVERED

Portfolio Overview

Challenge: Lack Real-Time Assessment for environmental health hazards

AFMS Force Health Protection Portfolio Overview

Ho Aug 2014
CITI Training

Each PI who submits a human research or exempt research protocol to the 59 MDW Institutional Review Board (IRB) is required to complete CITI training in human research subject protection. Associate Investigators (AI), other investigators, research project directors, coordinators, or assistants; and medical monitors listed on the protocol must also complete this training. The Office of Research Protocol Support must receive documentation of PI training before IRB review of the protocol. Documentation of training for AIs, other investigators, and the Research Monitor must be received before final approval of the study is granted. This is one of several ways that the IRB ensures that investigators possess the appropriate knowledge and skills required to conduct the research protocol.

The Basic CITI Course contains four groups of modules that pertain to biomedical or social/humanistic/behavioral research. To complete an initial Basic CITI Course, follow the following steps:

- Go to CITI website to access the training courses.
- Click either “Register Here” as a new user or enter your Username and Password if you previously registered for a CITI account. News users should select “USAF-Wilford Hall” from the Participating Institutions drop-down menu and then complete the remainder of the registration process (e.g., enters username, password, name, e-mail address).
- Consider the research category (human use or exempt) and focus (biomedical or social/humanistic/behavioral) that you plan to conduct and select the appropriate training group:
  - Group 1 – Biomedical research with human subjects
  - Group 2 – Exempt biomedical research with human subjects
  - Group 3 – Social/humanistic/behavioral research with human subjects
  - Group 4 – Exempt social/humanistic/behavioral research with human subjects.
- Complete each training module for the group that you selected. The passing score is 80% for each module. Complete the post-test. The passing score is 80%. If you score <80%, on each module or on the overall score, the failed training modules will reset to allow you to retake those modules.
- After you complete the training, download the course transcript and print it for your records. The Office of Research Protocol Support at the CRD will automatically receive notification that you completed the training.
- This training is valid for 3 years from the initial training date and must be re-accomplished prior to the 3-year expiration date by completing the CITI Refresher Course. If an investigator’s CITI training expires, they must be removed from the research study until the training is re-accomplished. If the Principal Investigator’s CITI training expires, the IRB may make a determination to suspend the research until the PI re-accomplishes the training. The IRB may not approve a Continuing Review Report or amendment to a study, if the PI’s training is not current. If a request is made to change the PI, the IRB may not approve the change, if the new PI does not have current CITI training.

The Refresher CITI Course is designed for investigators who previously completed a Basic CITI Course and are required to complete the 3-year re-certification requirement. To complete a Refresher Basic CITI Course, follow these steps:

- Go to CITI website to access the training courses
- Enter your Username and Password.
- Consider the research category (human use or exempt) and focus (biomedical or social/humanistic/behavioral) that you plan to conduct or are conducting and select the appropriate training group:
Complete each training module for the group that you selected. The passing score is 80% for each module. Complete the post-test. The passing score is 80%. If you score < 80%, on each module or on the overall score, the failed training modules will reset to allow you to retake those modules.

After you complete the training, download the course transcript and print it for your records. The Office of Research Protocol Support at the CRD will automatically receive notification that you completed the training.

Each PI, AI, other investigator, research coordinator or assistant, and Research Monitor must maintain current human research subjects protections training; therefore, if these individuals’ training lapses, the IRB will remove them from the study protocol. The IRB will not approve a continuing review report, amendment to the protocol, or request to change PI if the PI’s training is not current.

Contact the 59 CRD Office of Research Protocol Support for CITI training questions at:

59crd.protocol@us.af.mil
AALAS TRAINING INSTRUCTIONS FOR PRINCIPAL AND ASSOCIATE INVESTIGATORS

TO RECEIVE CREDIT FOR AALAS TRAINING, COMPLETE EACH COURSE LESSON AND EXAM IN EACH TRAINING MODULE

Go to AALAS Learning Library Website: https://www.aalaslearninglibrary.org/

1. Click Enroll now!

2. Under TYPE OF ENROLLMENT tab, “Are you enrolling yourself or a group?” Click Myself (I am purchasing an individual account or using an Access Code to join a group.) Click CONTINUE.

3. Under INDIVIDUAL ENROLLMENT TYPE tab, “Do you have an Access Code?” Click Yes, I have an Access Code. Click CONTINUE.

4. Under GROUP ACCESS CODE tab, “Enter your Access Code, which will associate your enrollment with your institution.” enter 2317159MDW/59CRD. Click CONTINUE.

5. Under USERNAME AND PASSWORD tab, complete all requested information. Click CONTINUE.

6. Under CONTACT INFORMATION tab, complete all items as applicable, required items are identified with asterisk. Click SUBMIT.

7. Under WELCOME tab, click CONTINUE. This should bring you to the homepage where you will use your username and password to login. Then ...

8. From the menu on the right side, click on Animal Care and Use Courses. [Here you will select the initial courses to take prior as part of the protocol submission process. Initial training remains current for three years.]

9. Initial course #1: click +AALAS Courses, click +Anesthesia, Analgesia, and Surgery, click Pain Management in Laboratory Animals and complete each course lesson and the course exam.

10. Initial course #2: from the menu on the left side, click on Animal Care and Use Courses, click +AALAS Courses, click +LATG Courses: 2007 LATG Training Manual, click LATG 06: Occupational Health and Safety (2007) complete each course lesson and the course exam.

11. Initial course#3: from the menu on the left side, click on Animal Care and Use Courses, click +AALAS Courses, click +ALAT Courses: 2009 ALAT Training Manual, click on the course required for the species used per the protocol and complete each course lesson and the course exam.

After the three-year initial training period, the following refresher courses are required:

1. Refresher course #1: click +AALAS Courses, click +US Mandates and Guidelines, click Public Health Service Policy on Humane Care and Use of Laboratory Animals and complete each course lesson and the course exam.

2. Refresher course #2: from the menu on the left side, click on Animal Care and Use Courses, click +AALAS Courses, click +Bioethics, click Ethical Decision-Making in Animal Research and complete each course lesson and the course exam.

Contact 59 CRD Office of Research Protocol Support at (210) 292-6095/2977 for AALAS training questions.

Please provide the Office of Research Protocol Support with a copy of your AALAS training transcript.
Cooperative Research and Development Agreement (CRADA)

A CRADA is a legal agreement between a federal agency and one or more nonfederal parties, such as private industry and academia, to collaborate on research and development. A CRADA is designated under the Federal Technology Transfer Act of 1986 (Public Law [P.L.] 99-502), which amended the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480). A CRADA offers each party the opportunity to leverage each other’s resources (i.e., personnel, services, facilities, equipment) when conducting research and development that is mutually beneficial. No federal funding is authorized for a CRADA. Through teaming efforts, the parties share the risks and benefits of the collaborative research and development. The end objective of a CRADA is to advance science and technology that meets Air Force mission requirements and has the potential for commercial applications.

A CRADA can:

- Optimize shared resources between all parties of the CRADA
- Facilitate sharing of technical expertise, ideas and information within a protected environment
- Facilitate sharing intellectual property resulting from the joint effort
- Expedite the commercialization of joint developed technology
- Protect any proprietary information provided by non-federal CRADA partners
- Allow all parties to keep research results confidential and proprietary for up to five years under the Freedom of Information Act
- Allow sharing of patents and patent licenses between the government and other CRADA partners
- Allow one partner to retain exclusive license to patentable research from the CRADA effort

When to Consider a CRADA

Not only can a CRADA be used to advance science and technology through research and development efforts, it can also be used to advance medical research technology and medical diagnostic and treatment methods. If you are contacted by an outside, non-federal agency (i.e., industrial manufacturers, pharmaceutical labs, academia, etc.) requesting government assistance to help evaluate a medical device, drug or intervention, then this may require a medical CRADA agreement. The Air Force Surgeon General (AF/SG) has stood-up a Technology Transfer Office under the oversight of AFMSA/A5, which supports medical research for the entire AF Medical Service. The Technology Transfer Office has the oversight for medical CRADAs and Material Transfer Agreements (MTAs). DO NOT proceed with any collaborative research efforts with an outside entity until you have contacted the Technology Transfer Office for regulatory guidance. The points of contact to discuss CRADA and MTA requirements are:

Sherrilynne Cherry: sherrilynne.cherry@us.af.mil; 210-292-2570
AFMS Technology Transfer Focal Point/ORTA/SBIR
AFMSA/SG5M
AFMS T2 Email: afmsa.sg5m.technologytransferoffice@us.af.mil
AFMS SBIR Email: afmsa.sbir@us.af.mil
APPENDIX F

Investigator Approaches ST with Whitepaper, Proposal, or Protocol

**S9 ST/CRD**
- CIP and non-CIP Integrated Review
  - Research Alignment
  - Mission fit per DoDI, JPC/AFMS Gaps/GHSE

- PI is USAF (can be GHSE Fellow/Resident or AF/GHSE Faculty)*
- Protocol and Budget

**GHSE (CIP) Project**
- Required Funding Less than $50K
  - Possible GHSE Consideration at SAMMC (S9S GHSE)
  - Review for Alignment with CAMD, ERCRC, etc. Ongoing Efforts
  - Funding by CRD S9S GHSE

- Required Funding More than $50K
  - Review for Alignment with CAMD, ERCRC, etc. Ongoing Efforts
  - Submit for S9S GHSE Intramural Call (GHSE at SAMMC)

**R&D (Non-CIP) Project**
- 69 MDW/ST
  - Research Alignment
  - Does project fit AF Mission?
  - Meet with ST Scientists to discuss funding opportunities and proposal/protocol development

- 69 MDW/ST Intramural Call
  - Review eligibility for outside funding opportunities (JPC, CMDRP, AFMS, etc.)

- ST can assist with grant package development and submission via grants.gov

- Submit to 59 MDW/ST Intramural Call

- Refer to 59 MDW/ST Intramural Call for eligibility
- Proposed effort must be 3 years or less

*If PI is AF/GHSE Faculty, then AI must be USAF GHSE Fellow/Resident.

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Planning Ahead for Protocol Requirements, Agreements, and Contracting Actions

**Project Management**
- Meet with ST Project Manager to schedule 59 ST/CRD Kick-off Meetings:
  - Regulatory Compliance Review - will dictate which Protocol Office for Submission
  - Review Project Milestones, Deliverables, Budget, and relevance to AF Priorities
  - Review Project Protocol & Contracting Needs, and Other Research Support
  - Review Proposed Collaborations/Need for Partnership Agreements

**Animal Facility Required**
- Stand-up Animal Facility Optimization Group for Recommended Lab Selection
- S9 ST/CRD Facility
- TSRL
- USAISR/BHT
- Contract for Services*

**Laboratory Support Required**
- Submit to Lab Optimization for Recommended Lab Selection
- S9 ST/CRD Facility
- CAMD
- Other DoD Lab
- USAISR/BHT
- DCI/SAMMC
- Contract for Lab Services*

**Other Research Support**
- Statistical Analysis
- 59 ST/CRD can support
  - External Collaborator
  - Academia
  - Contract for Services*

- ORTA Review for Agreement
  - *Will Require Contracting Actions
  - Protocol Office other than through 59 ST/CRD Facility