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FOREWORD

The 59th Medical Wing Chief Scientist provides the strategic vision, direction, oversight, project management support and technical resources to advance medical modernization efforts with a unique focus on research activities. The research portfolio is requirements-driven to address unique military scientific needs in trauma critical care, clinical and rehabilitative medicine, diagnostics, simulation training, and therapeutics and medical modeling. The goal is to advance DoD Joint capabilities and improve military health and readiness from the battlefield to the market-place through interfacing with partners in the Services, academia, private sector, and other government agencies to transition scientific findings to best practice in the operational environment and at the patient bedside.

This guide is a quick reference for the numerous specialized Principal Investigators involved in military medical research in and around the San Antonio, Texas. Additional information regarding the 59th Medical Wing, our office and research portfolio is provided at: http://www.59mdw.af.mil/Home.aspx; http://www.59mdw.af.mil/Units/ChiefScientist-ST.aspx; https://kx.afms.mil/kx8/59MDWScienceAndTechnology/Pages/home.aspx;

Debra M. Niemeyer, PhD, DAF
Chief Scientist, 59th Medical Wing
INTRODUCTION
The purpose of the principal Investigator Handbook is to aid researchers in 1) planning, proposing, preparing, funding, and executing research studies; and 2) reporting research and program initiatives conducted by the 59th Medical Wing (59 MDW) and overseen by the Office of the Chief Scientist, Science and Technology Office (59 MDW/ST) in the San Antonio Market.

This handbook is intended to serve as a guide for new and experienced investigators alike. However, it is not meant to be all-inclusive due to the frequency of program, 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 affecting them (e.g., research proposal development, protocol formats, suspense dates, briefings, contracts, etc.). The 59 MDW/ST staff pledges to do all they can to assist investigators and directors with the development and execution of proposals, initiatives, projects, and programs.

PURPOSE
All clinical and translational research conducted within the 59 MDW and/or supported by 59 MDW/ST irrespective of funding type and source is overseen by the 59 MDW/ST office. Furthermore, 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, throughout the San Antonio Market or other sites, as applicable.

Research should apply science and technology to produce solutions that address military relevant gaps and identified needs.

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, and advance capabilities across the global health system in support of the Quadruple Aim.

The Chief Scientist provides leadership and develops high-level collaborations between Services, Department of Defense, local, national and international governments, academia and industry, and research, development, test, evaluation and acquisition organizations. The Chief Scientist oversees and manages a dynamic portfolio to meet organizational needs, while leveraging partnerships to develop tailored investments that advance state of the art solutions for “world class” precision medical care with an emphasis on mission aligned research in En Route Care, Trauma, Resuscitation and Stabilization; Diagnostics, Therapeutics and ‘Omics; Modeling Simulation Training; Clinical Rehabilitative Medicine; and Clinical Investigations. The Wing Chief Scientist is the Alternate Institutional Official charged with the responsibility for the protection of human research subjects participating in research as part of the 59 MDW Human Research Protection Program.

The Chief Scientist's Office, also provides scientific, technical, biostatistical, bioinformatics, program management, regulatory compliance, and translational research support and guidance for investigators and their collaborators to facilitate research that addresses unique scientific needs of the 59th Medical Wing, Air Force, Joint community, Department of Defense and the Nation. conducted by This specialized expertise enables researchers to exploit new knowledge while developing, evaluating, and integrating applications of innovative technologies to provide the very best patient-centered care from the point of injury in the combat theater to definitive care with the ultimate goal of maintaining and restoring warfighter and beneficiary health, and building warrior medics to address present and future mission challenges.

A core function of 59 MDW/ST is to facilitate clinical research that fulfills knowledge and technology gaps. Consequently, ST plays a vital role in the lifecycle of all research performed within the Chief Scientist’s
The 59 MDW is the largest clinical and translational research arena in the Air Force. ST receives and executes research funds and provides expert assistance to define military-unique capability gaps, identify requirements-based, and conduct and manage research programs and projects. ST conducts and facilitates research through the acquisition of resources (people, materials, etc.) to enable investigators to successfully generate knowledge and technology products that fill capability gaps at home and abroad. Additionally, ST assists investigators in obtaining funding of all clinical studies and analyses basic- to-applied- research, advanced development, testing, sustainment, and fielding products. ST provides leadership and support for best practices, innovation, education, training, translational research, and moving scientific findings to the operational environment and patient care setting.

**PROTOCOL DEVELOPMENT**

59th Medical Wing investigators and their research teams are required to comply with the regulatory requirements governing human subjects and animal research, as applicable to their study. The 59 MDW/ST Clinical Investigations and Research Support (CIRS) Division provides technical, regulatory and administrative support and guidance to investigators throughout the life cycle of the research protocol, to include human subjects, animal, and laboratory (bench) studies. CIRS also conducts research determinations for exempt human subjects’ research, and non-research studies (for example, Process Improvement/Quality Improvement projects).

Researchers conducting human subjects’ research should be aware that Institutional Review Boards (IRBs) have merged to form the San Antonio IRB (SA IRB) by order of LTG Ronald Place, Director, Defense Agency (DHA), the 59 MDW and Brooke Army Medical Center (BAMC). As of February 2022, 59 MDW investigators who conduct human subjects research at BAMC and/or WHASC must submit protocols through the SA IRB as the IRB of Record for approval and oversight of all non-exempt human subjects research. The SA IRB is managed by BAMC administrative staff. For those 59 MDW investigators that conduct human subjects research at WHASC (i.e., studies involve WHASC beneficiaries) or that involve basic military trainees, the CIRS’ Office of Research Protocol Support (CIRS) remains the primary POC for protocol submission assistance and regulatory management for the entirety of the study. For personnel assigned to the 59 MDW-who conduct human subjects research at BAMC (i.e., studies involve BAMC beneficiaries), the primary point of contact for protocol assistance is the BAMC Human Research Protections Office.

For animal research to be conducted at CIRS the researcher(s) must submit the protocol to the 59 MDW Institutional Animal Care and Use Committee (IACUC) for approval. Animal studies are managed and supported by CIRS staff. It should be noted in most cases IACUCs are tied to the facility in which the animal use will be conducted – for example, the IACUCs for the U.S. Army Institute for Surgical Research and the Tri-Service Research Laboratory are located at those respective facilities on Fort Sam Houston. Investigators interested in developing an animal use research protocol should first meet with the CIRS Attending Veterinarian (AV) to determine if the CIRS animal facility can support the appropriate animal model, the complexity of the study, and the timelines for animal support. If the proposed research cannot be accomplished at CIRS, staff may assist with recommendations for locating an alternate animal use facility that can support the research.

The time needed for study approval by the SA IRB or IACUC can vary depending on the complexity of the study design, specific organizational policies, and/or if a second level (headquarters) review and approval is required. As a result, the 59 MDW/ST highly encourages investigators to initiate this process as early as possible. The ST staff are committed to helping at every step of the research review process as previously described.

Research related templates (e.g., research protocols, HIPAA, Informed Consent Document, etc.) required to obtain approval and/or determinations for human subjects or animal research are regularly updated and available through the Office of Research Protocol Support either by emailing your request to usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil or through the AFMS Knowledge Exchange: https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx. Templates required by the SA IRB are also available at this link (use Internet Explorer to access):
**LITERATURE SEARCH**

A literature search is a systematic search of all relevant literature on a specific topic. Relevant literature can include journal articles, conference abstracts, books or book chapters, clinical trial registries and more. A review of literature provides assurance to protocol or funding reviewers that the study is new and innovative. The literature review also provides information on similar studies and methods to improve design of the research study.

- Support – The 59 MDW Medical Library can provide articles not available on the AF website. For assistance send an email to usaf.jbsa.59-mdw.mbx.wing-medical-library@mail.mil
- Requests for guidance on, or assistance with literature reviews can be submitted to the ST Office.

**PROTOCOL NARRATIVE**

An essential first step is to develop an outline that includes an overall research question/hypothesis, and 2-3 specific aims that address knowledge gaps to demonstrate to the reviewer how the research will answer the research question or test the hypothesis. The background section should reflect a command of the knowledge of the topic and existing gaps in the literature. The background section should include the problem, the significance of the problem, the current standard of care, limitations with the current standard of care, and how the propose study expands on or refutes the current standard of care. If the proposed study is an expansion or continuation of previous research, the background should include a synopsis of the research outcomes thus far and the reasoning for continuing that line of inquiry. The objectives and/or hypothesis section is next, followed by the experimental outline. A short paragraph on the military relevance of the research should be anticipated and prepared, as well as a transition strategy. 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 scientists that offer support and guidance in composing the study design and data analysis sections of the research protocol.

Additionally, scientists are available to review human subject or animal research protocols before submission for regulatory committee approval. 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 subject matter expert (SME) to assist 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 SME will assist with any necessary coordination.

**REGULATORY-REQUIRED TRAINING TO CONDUCT RESEARCH**

All research investigators and research staff seeking to conduct research involving human subjects, both at WHASC and BAMC, are required to complete role-based Office of the Under Secretary of Defense (Personnel & Readiness) [OUSD(P&R)] Collaborative Institutional Training Initiative (CITI) training before submitting their research protocol to the SA IRB. This training can be easily completed at any workstation with a “.mil” account. For additional details, please refer to Appendix A.

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

For FDA-sponsored IND and IDE studies, PIs are required to complete CITI Good Clinical Practice (GCP) training. GCP training is mandated in the International Conference on Harmonization (ICH) document, “E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1) Guidance for Industry” accessible at: https://www.fda.gov/media/93884/download.
PRELIMINARY REVIEW

Investigators may contact the CIRS Office of Research Protocol Support to schedule a regulatory pre-review for human research protocols prior to submission to the SA IRB. Once complete, the CIRS support staff will forward the protocol to the SA IRB for final administrative review and consideration by the SA IRB. Protocols are accepted by the SA IRB on a rolling submission basis. Investigators should contact the SA IRB support staff for approximate timelines.

The investigator can meet with SA IRB personnel to address any questions or concerns before the monthly SA IRB meeting. During the monthly SA IRB meetings protocols are reviewed, approved, conditionally approved pending changes, tabled/deferred, or disapproved. In the case of a deferral or disapproval, the investigator should work with the CIRS staff to address SA IRB concerns. The ST staff is also available to assist with revisions.

All animal research protocols are submitted to the 59 MDW IACUC Office five (5) weeks plus one day prior to the next scheduled monthly IACUC meeting. Within the first 2 weeks following submission, the investigator can meet with the CIRS staff for an optional (but highly recommended) pre-review to address any questions or concerns before the monthly IACUC meeting. At monthly IACUC meetings determinations are made regarding approval, modifications required to secure approval, or approval withheld. In the case in which an approval is not immediately granted, the CIRS staff is available to assist with revisions.

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 HRPP Institutional Official (IO) recognized by Defense Health Agency’s Office of Research Protections (DHA ORP). Day-to-day HRPP IO responsibilities for the protection of human research subjects are delegated to the Alternate Institutional Officials (AIO), currently the 59 MDW Chief Scientist and Chief Medical Officer (CMO).

SAN ANTONIO INSTITUTIONAL REVIEW BOARD

The mission of the SA IRB, like other DHA IRBs, is to protect the rights and welfare of human research subjects recruited to participant in non-exempt human research protocols at the 59 MDW and other DoD or non-DoD sites in which the SA IRB is the IRB of Record. The 59 MDW Exempt Determination Officials (EDOs) currently make official determinations regarding whether activities involving human subjects are research or not. Exempt research that involves human subjects or research that involves human subjects requires SA IRB approval prior to initiation (32 CFR 219 and DoDI 3216.02).

Research Teams

Each member of a research team is responsible for protecting human research subjects. Team members may range from the PI, associate investigators (AI), research assistants, research coordinators, and/or other research staff. Each member of the research team has a strict obligation to:

- Comply with all IRB decisions and organizational requirements.
- Adhere rigorously to the protocol as approved.
- Inform investigators and the IRB of events or unanticipated problems involving risks to research subjects or others.
- Oversee the adequacy of the informed consent process; and
Take whatever measures necessary to protect the safety and welfare of research participants.

**Research Participants**

Research participants have rights and responsibilities when participating in a research study, to include:

- Ask questions and seek clarification about the information researchers present to them so they can make an informed decision about participation.
- Make every reasonable effort to comply with protocol requirements.
- Inform the investigators of any research-related problems, issues, or concerns that arise, for instance, if they are unable to meet the requirements of participation; and
- Suggest changes to the research or informed consent, where appropriate, to help improve compliance or the participant experience.

**Ombudsman**

Special consideration must be given to the recruitment process for military personnel. In accordance with DoDI 3216.02, when research involves greater than minimal risk, an Ombudsman must be employed when conducting group briefings with active duty personnel to ensure they understand that participation is voluntary and to ensure the recruitment/consenting process is free of undue influence or coercion.

The use of an Ombudsman may be recommended in other situations as well, especially when young, enlisted service members are recruited who are trained to follow orders. Service members are trained to act as a unit, therefore peer pressure should be considered and mitigated, where possible.

**All Members of the Organization**

- To ensure an effective HRPP, all members of the community must promptly report any serious or continuing noncompliance with applicable regulatory requirements or determinations of the SA IRB of which they become aware, whether or not they themselves are involved in the research. Individuals may also notify the SA IRB or the 59 MDW Human Protections Administer (HPA) directly with any compliance concerns regarding the research process or procedures.
- In addition to the responsibilities specifically delegated by the IO, each member of the 59 MDW community plays a role in ensuring the ethical and responsible conduct of human subject research.
- All individuals within the 59 MDW have the responsibility to:
  - Promote a research culture that respects and protects research participants.
  - Maintain awareness of the organizational policies including the definition of Human Research.
  - Consult the Exempt Determination Official (EDO) when there is uncertainty about whether an activity is Human Subject Research (HSR).
  - Not conduct Human Research or allow Human Research to be conducted without review and approval by the SA IRB; and
  - Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the 59 MDW AIO or HPA.

**Helpful IRB Processing Tips**

- Engage the Office of Research Protocol Support and the SA IRB support staff early in the process to review a checklist of documents needed specific to the protocol type.
- Establish an EIRB account early in protocol development, as all documentation will be uploaded and managed within this system. The CIRS staff can guide investigators in this process.
- Allow enough time for protocol development to ensure consistency and completeness.
- Ensure protocol and Informed Consent Document information matches exactly (e.g., risks/benefits, study procedures/methods). Document version control is extremely important.
- Though the SA IRB Committee is diverse and well-educated, both formally and informally, there is the potential they are not familiar with the research being reviewed. Avoid the use of technical or field-specific jargon and acronyms whenever possible. If use of jargon or acronyms is necessary, then clearly define each...
term the first time it is 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 study benefits outweigh the risks or why the risks are deemed 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 or CIRS 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 specifics regarding who will be monitoring the participants, data collection, frequency of monitoring, and provide a clear description of the safety assurances.
- Principal Investigators (PIs) are required to maintain a regulatory file/binder of all approved documents and correspondence from the SA IRB and other regulatory agencies.

Frequently Asked Questions for HRPP/IRB:

What to Expect at the SA IRB Meeting?
The Board will review the study and all study-related documents then vote to approve the study, conditionally approve the study, table/defer the study or disapprove the study. The PI or their representative may receive prior notification to attend the IRB meeting to address any questions or concerns regarding the study.

What Happens if I Receive a Conditional Approval Letter?
A study is conditionally approved when specific SA IRB-directed stipulations and/or changes are required for the protocol. The revisions suggested in the SA IRB conditional approval letter must be completed within 30 days or the study may be administratively withdrawn. The changes requested by the SA IRB must be completed in track-changes, highlighted or colored text; and returned to the SA IRB through EIRB for subsequent review by a designated IRB reviewer or for review by a fully convened SA IRB meeting.

The Final Protocol Approval Letter
An SA IRB final approval letter is granted if the study is approved without changes; and all SA IRB-directed stipulations and/or changes have been made and submitted to the SA IRB for final review. The final requirement prior to proceeding with IRB-approved human subjects research is obtaining 59 MDW “institutional authorization.” This is granted by the 59 MDW AIO, who issues an institutional authorization to proceed memo.

What are IRB Continuing Review (Progress) Reports?
Researchers conducting IRB-approved research may be required to provide a Continuing Review (CR), depending on the review type. All studies deemed greater than minimal risk will be required to submit a CR at least annually. 

Based on the risk level of the study, it may be necessary to provide CR reports more frequently than annually. Investigators might receive reminders to submit their CR submission as a courtesy, however, it is the PIs responsibility to submit the CR at least 60 days before the official expiration date of IRB approval to allow sufficient time for IRB review. Please note, failure to complete and submit required reports may result in suspension or termination of the study. Important guidance is provided in the approval memo, thus PIs are highly encourage to review it for further direction.

Studies not requiring full IRB approval or continuing review (e.g., exempt studies) may have a periodic review requested by the 59 MDW at least annually. The 59th MDW HRPO office will contact the study team to request a periodic review be completed.
Principal Investigators and Research Staff Responsibilities
The primary responsibility of PIs and research staff is to safeguard the rights and welfare of research participants. The rights and welfare of participants’ takes precedence over the goals and requirements of society and research. Any questions related to this responsibility or the policies and procedures for protection of human subjects, should be directed to the 59 MDW Human Protections Administrator or the SA IRB Office.

Financial Conflict of Interest (FCOI)
For protocols requiring SA IRB review, the IRB submission must include the EIRB Conflict of Interest Form. To meet 59 MDW HRPP requirements, any 59 MDW personnel (PIs and research staff) engaging the 59 MDW in human subjects research must also disclose any conflict of interest on the 59 MDW Form 14, Financial Conflict of Interest Disclosure Form to the 59 MDW COI Manager via encrypted email.

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 usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil for review and routing to the 59 MDW Scientific Ethics Subcommittee, if necessary. All researchers with a significant conflict of interest will require a COI Management Plan for approval by the 59 MDW AIO. If the plan changes any component of an IRB-approved protocol, SA IRB review will also be required.

Researchers and research staff must review 59 MDW specific COI training every 4 years as required by 59 MDW 51-501 Managing Conflict of Interest in Research. Certificates of training must be mailed to the COI manager at to usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
The 59 MDW Animal Care and Use Program (ACUP), to include the IACUC, exists to protect the welfare of animals used in the conduct of research and training in accordance with Federal regulation, DoD policy, and accreditation standards. 59th Medical Wing Instruction 40-402, Animal Care and Use in Clinical Investigations, Training, and Research & Development, outlines the 59 MDW ACUP and investigators’ responsibilities when conducting research or training. All investigators are required to keep protocol binders current with correspondence from the CIRS’ Office of Research Protocol Support, Curricula Vitae (CVs), AALAS training and certifications, and data collection sheets.

Frequently Asked Questions for IACUC:

What to Expect at the IACUC Meeting?
A PI or representative is invited to the IACUC meeting to provide a general overview of the animal use proposal to the IACUC and answer any questions or concerns. This is required for GHSE investigators seeking Clinical Investigations Program funding; otherwise, it is optional, but highly encouraged. The board then reviews the study and all study-related documents and votes to approve the study, require modifications to secure approval, or withhold approval (disapprove). Modifications can be reviewed either by Designated Member Review or Full Committee Review, the process by which is determined by IACUC membership vote.

What Happens if I Receive an IACUC Letter Requiring Modifications to Secure Approval?
A protocol 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 should be completed using track changes or highlighted 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.
What Are IACUC Continuing Review (Progress) Reports?

All Principal Investigators for research and training protocols 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 reports that are more frequent for certain studies (e.g., following model development animals). Please note that continuing reviews are required annually by DoD policy; failure to complete and submit required reports may result in suspension or termination of the study.

The Final IACUC 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. At a minimum, all training protocols must be submitted to AFMRA 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 rewritten and resubmitted for as a brand new protocol.

CIRS QUALITY ASSURANCE/QUALITY IMPROVEMENT

Quality Assurance/Quality Improvement

Quality assurance and quality improvement (QA/QI) for both human subjects and animal protocols are the responsibility of the 59 MDW Research Compliance Office. The Research Compliance Officer monitors 59 MDW research involving the use of human subjects approved by the SAIRB. 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 SA IRB. Compliance personnel also conduct post-approval monitoring of research involving the use of animals, which may include direct audits of study records at the study site; contact with the PI; 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 obtained using many different mechanisms. Most often funding is received by the 59 MDW via a Funding Authorization Document (FAD). For funds to be sent to ST, the 59 MDW must be designated as a site. 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 (EEICs). 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.

Research, Development, Test, and Evaluation (RDT&E)

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

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

### Operation and Maintenance (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. An example of O&M funding for research are those funds awarded by CIRS for studies conducted to fulfill Graduate Health Sciences Education scholarly activity requirements. These funds may be requested throughout the fiscal year, and are awarded on a first-come/first-served basis. Centralized O&M award calls for proposals may also be offered by DHA’s Clinical Investigations Program Office.

The above descriptions require interpretation when applying them to Defense Health Program (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 on technology maturity, or for feasibility studies on technology application, or to fund proposals submitted to the Broad Agency Announcement (BAA). Research and Development (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 product 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 types 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) can 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 for use with travel in accordance with MDWI 51-601. In accordance with MDWI 51-501, individuals conducting research must disclose gifts, including gifts of travel, having a market value exceeding $20 per source per occasion and gifts from a single source with an aggregate market value exceeding $50 in a calendar year.

**Funding Opportunities**
The 59 MDW/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 funding outside the 59 MDW collaboration, the ST Office is the point of contact (POC). ST has expertise in coordination of Cooperative Research and Development Agreements (CRADAs) and other research agreements, and interfaces with the Office of Research and Technology Applications (ORTA).

**Formal Proposal Process.** The formal competitive proposal process is the usual way to receive funding. This section outlines different types of proposal opportunities, the proposal submission process, and the process of acquiring funds.

**Proposal Opportunities.**
1. The first type of proposal opportunity is the Broad Agency Announcement (BAA); BAAs solicit proposals to address specific agency research interest which include selection criteria for acceptance. These solicitations encourage widest dissemination to researchers and interties capable of fulfilling the specific government’s need.
2. A second proposal opportunity is a Request for Information (RFI). An RFI is used when an agency does not intend to award a contract but wants to receive information on prices, delivery, capabilities, and other market information for planning purposes. Responses to these notices are not offers and cannot be accepted by the government to form a binding contract.
3. The next is a Request for Proposals (RFP). An RFP is used in negotiated acquisitions to communicate to other prospective performers to solicit proposals.

**Proposal Submission.**
Investigators respond to the requests by carefully following the instructions given by the sponsoring agencies. Sponsors often require a white paper, letter of intent, or pre-proposal prior to a call for full proposals. A white paper is usually no longer than five pages and allows sponsors to quickly evaluate the suitability and desirability of the proposed research. The more compact format of the white paper is meant to minimize labor and cost associated with a full proposal. If the white paper is selected, the sponsor requests a full proposal. Sponsors may also require a statement of work.

**Funding Process.**
The funding process begins as soon as the Investigator drafts a statement of work and budget estimate for a proposal, and it continues all the way through to completion of the project. The proposal has both a financial aspect (assuring the budget is accurate) and a technical aspect (technically sound and can be accomplished within the budget and time frame allotted).
**Government Agency-Initiated Project Funding.**
Sponsor-initiated funding is the easiest type of funding to acquire. This funding is usually initiated based on a need within the DHA or Air Force.

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 http://www.grants.gov, http://grants.nih.gov; http://www.arl.army.mil; beta.SAM.gov; and http://cdmrp.army.mil.

**CIRS Clinical Investigation Program (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, but cannot be used to purchase manpower. Travel is limited to DoD’s annual Military Health System Research Symposium if presenting. Submit requests to the Director, CIRS.

**Defense Medical Research and Development Program (DMRDP)**
As directed by the Office of the Assistant Secretary of Defense for Health Affairs [OASD (HA)], the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for the six DHP core research program areas listed below.

Each of these major research program areas are strategically guided by a committee, called a Joint Program Committee, or JPC, which consists of DoD and non-DoD medical and military technical experts. These experts work through coordinated efforts to translate guidance into research and development needs. They also have key responsibilities to make funding recommendations and provide program management support. Within the USAMRMC, operational support for the JPCs are provided by multiple execution agents, including the CDMRP, individual laboratories, and advanced developers. CDMRP provides program and award management support primarily for basic through translational research (Program Elements 6.1 through 6.3) and works closely with the JPCs to transition products to advanced development. For additional details, visit https://cdmrp.army.mil/dmrdp/default.

- JPC1 – Medical Simulation and Information Sciences Research Program
- JPC2 – Military Infectious Diseases Research Program
- JPC5 – Military Operational Medicine Research Program
- JPC6 – Combat Casualty Care Research Program
- JPC7 – Radiation Health Effects Research Program
- JPC8 – Clinical & Rehabilitative Medicine Research Program

**Congressionally Directed Medical Research Program (CDMRP)**
The CDMRP originated in 1992 via a Congressional appropriation to foster novel approaches to biomedical research in response to the expressed needs of its stakeholders, the American public, the military, and Congress.

The CDMRP fills research gaps by funding high impact, high risk and high gain projects that other agencies may not venture to fund. While individual programs are unique in their focus, all of the programs managed by the CDMRP share the common goal of advancing paradigm shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. The CDMRP strives to transform healthcare for Service Members and the American public through innovative and impactful research. For more information on CDMRP and funding opportunities visit https://cdmrp.army.mil/default.
National Institute for Health (NIH) Multi-Institutional Announcement(s)
- This type of study may include DoD facility as collaborators only, not primary submitters.

U.S. Army Medical Research and Development Command's (USAMRDC) Broad Agency Announcement (BAA)
- The USAMRDC BAA 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.

711th Human Performance Wing Broad Agency Announcement BAA
- The Air Force Research Laboratory, 711th Human Performance Wing (711 HPW) BAA is open for limited time.

Tri-Service Nursing Research Program (TSNRP)
- TSNRP exclusively provides support for rigorous scientific nursing research and Evidence-Based Practice (EBP) activities for military relevant needs.
- For more information visit: [https://www.usuhs.edu/research/centers/tsnrp/research/funding-opportunities](https://www.usuhs.edu/research/centers/tsnrp/research/funding-opportunities)

Award Categories Include:
- **Graduate Research or Evidence-Based Practice Award**
  - Purpose of Award: Funding for dissertation, thesis, or final project
  - Eligibility Requirements:
    - Active Duty or Reserve nurse in the U.S. military
    - Master’s or doctoral degree student
    - TSNRP will be the sole source of funding for the project
    - Research or EBP project have not started prior to award issuance
  - Direct and Indirect Cost Limit: $40,000 per award for up to 12 months
  - Tuition, faculty, or consulting fees are not included in this award
- **High-Priority Research Award**
  - Purpose of Award: Funding to complete a rigorous research study that clearly addresses one of the following topics, specific for military nursing (subject to change):
    - Nursing policies and practice (guidelines, staffing models, etc.) to care for ill and injured warfighters in austere environments for extended periods of time
    - Nursing care in the initial resuscitation/forward surgical setting to include holding capacity, impact of environment (injuries occurring in water, scarce resources, etc.), clinical practice guidelines, and training/competency gaps
    - Clinical skill development and sustainment training platforms, especially the use of simulation and civilian-military partnerships
    - Nursing role for proactive management of the health of the warfighter in both the home unit and deployed locations
    - Impact of military health system consolidation on nursing and patient outcomes, to include recruitment, retention, teamwork, and unit cohesion
    - Impact of medical surgical staffing models on quality, safety, and nurse satisfaction measures within the military healthcare system
    - Optimal pathways to transition from new graduate to a fully deployable nurse
    - Outcome measures for military nursing care provided in the inpatient, ambulatory, and deployed settings that could be compared with civilian nursing outcome measures
    - COVID-19 nursing practice areas
  - Eligibility Requirements:
    - A PhD prepared nurse must serve as the Principal Investigator
    - Active Duty, National Guard, Reserve Nurse, or retired U.S. military nurse
• If the PI is a retired military nurse, an active duty military nurse must serve as an associate investigator
  o Direct Cost Limit: $450,000 per award for up to 2 years

• Novice Research or Evidence-Based Practice Award
  o Purpose of Award: Funding for a mentored project specifically for those with limited research or formal evidence-based practice experience.
  o Eligibility Requirements:
    ▪ Active Duty Nurse, Reserve, National Guard, or retired nurse in the U.S. military (research)
    ▪ If the PI is a retired military nurse an active duty nurse must serve as an associate investigator
    ▪ A PhD-prepared team member is required for research applications.
  o Direct Cost Limit:
    ▪ $350,000 for up to 2 years for Research applications
    ▪ $200,000 for up to 2 years for Evidence-Based Practice applications

• Evidence Based Practice Award
  o Purpose of Award: Either the development of a Clinical Practice Guideline to improve outcomes, standardize care, and promote cost-effective care OR the implementation and evaluation of a Clinical Practice Guideline to improve outcomes, standardize care, and promote cost-effective care
  o Eligibility Requirement: Active Duty, Reserve, National Guard, in the U.S. military
  o Direct Cost Limit: $250,000 for up to 2 years

• Initial Research Award
  o Purpose of Award: Conduct an initial stage of a research study that meets TSNRP priorities.
  o Eligibility Requirements:
    ▪ Active Duty, Reserve, National Guard, or retired nurse in the U.S. military. If the PI is a retired military nurse, an active duty nurse must serve as an associate investigator
    ▪ Completed or successfully finishing a funded research study or has been first author on two data-based refereed publications, post-dissertation
  o Direct Cost Limit: $450,000 for up to 2 years

• Follow-on Research Award
  o Purpose of Award: Expand a promising TSNRP-funded initial research study, especially the translation of emerging knowledge into clinical practice
  o Eligibility Requirements:
    ▪ Active Duty, Reserve, National Guard, or retired nurse in the U.S. military. If the PI is a retired military nurse, an active duty nurse must serve as an associate investigator
    ▪ Receipt of a TSNRP-funded research study that is currently underway or completed within the previous 3 years
  o Direct Cost Limit: $450,000 for up to 2 years

Project funding will be in the form of a sub-award with the Geneva Foundation

Additional Mechanism for Identifying Funding Opportunities.
Another mechanism for identifying funding opportunities is the public forum, including Grants.gov, where government organizations post grant opportunities. These postings are usually in the form of RFIs, of which some may be intended for businesses. 59 MDW/ST cannot directly respond to opportunities directed at
businesses, however, those opportunities can be used to identify a need or requirement of a DoD organization.

**Applying for Grants via Online Grant Submission Sites**

Online grant submission systems: eRA Commons; Grants.gov; and Electronic Biomedical Research Application Portal (eBRAP), which support federal research awards.

Principal Investigators (PIs) who are planning to apply using one of the online grant mechanisms above, should contact the ST Business Official (BO) regarding submission intent as soon as possible. The proposal review is to be completed prior to acceptance of PI affiliation requests and generation of letters of support. The BO will guide PIs through the specific steps for the internal review process and online submission.

The proposal review consists of the ST staff conducting a technical and programmatic review of proposals providing expert advice and counsel concerning merit, adherence to call requirements, and alignment with the wing research portfolio and the broader DHP corporate research investment.

For more information, please contact the 59 MDW/ST, Director, Program Analytics & Research Cell at (210) 292-2303/2097.

**RESEARCH PROPOSAL**

All funding applications require a research proposal and, if applicable, a regulatory committee approval (e.g., IRB or IACUC). 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 present a condensed 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 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 reviewed prior to selection 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):

- Abstract
- Background
- Military Relevance
- Technical Program Summary/Methods
- References
- Milestones/Deliverables
- Facilities/Equipment/Experience
- Subcontracts
- Cost proposal (see below budget)
- Bio sketch of Investigator and Co-Investigator
- Letter of Support
- QUAD Chart
- Transition Strategy
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. A Contract Data Requirements List (CDRL) is also required which 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 Labor Categories can include: Research Nurse, Coordinator, Research Assistant, Clinical Research Scientist, Epidemiologist, Statistician, Veterinary/Surgical Technician, or 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, Supply Custodians that are listed on the Project Funds Management Record (PFMR) Letter (i.e., Supply Custodian Appointment Letter) are the only individuals that are granted DMLSS (Defense Medical Logistics Supply System) access to order supplies for any given research project which is identified/approved by the PM prior to routing the letter for signatures. 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 ST-managed O&M funded research 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 at research study closure. For funded projects, the ST Office will assist with the quarterly report and other requested reports. For DMRDP funded projects, the JPC 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 an annual Research Program Review conducted by the 59 MDW Chief Scientist to assess scientific and programmatic progress. This review will include higher level representation, and Major Command (MAJCOM) Surgeon representatives. These reviews provide an in-depth overview of the Wing and the research portfolio to baseline programs and assesses progress on addressing military relevant capability gaps. These reviews are critical in preparing reviews for the 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 between ST staff the PI, and the research team prior to project initiation to introduce reporting requirements. Check with the Program Manager for reporting requirements and formats.

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

**59 MDW/ST Quarterly Progress Update Reports (QPUR):**
The QPUR is to update the funding organization on current status of cost, schedule and performance.

**CDMRP/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 Development Command (USAMRDC). These agreement awards have special terms and conditions clauses to include the technical reporting requirements.

**Intramural Quarterly Reporting Requirements:**
Quarterly reports are required to update the funding agency on status of the project, budget and research presentations and publications. At the initial notification of award, the organization will provide a template for the quarterly report. The ST Office can assist the investigator with these quarterly reports. To facilitate the reporting, please provide copies of abstracts, journal articles, book chapters or any publications to your Project Manager (PM) at the time of publication acceptance.

**Clinical Investigations Program (CIP) Quarterly Updates:**
The 59 MDW CIP collates data on 59 MDW medical research writings and oral presentations prepared by personnel assigned to the Wing on a quarterly basis. The report includes program accomplishments and significant events, significant studies, presentations, and publications. GHSE (Graduate Health Science Education) residents and fellows may be contacted by CIRS staff for information required for the quarterly report. Additionally, these research writings and presentations are uploaded to Defense Technical Information Center (DTIC) on a regular basis. Refer to 59 MDWI 41-108 for more information.

**Protocol Final Reports:**
Protocol final reports are SA IRB and IACUC required documents. An annual Continuing Review (Progress) report template is in EIRB for human subjects research protocols. The CIRS Office of Research Protocol Support can provide an annual (progress) report template for animal research. The purpose of the report is to summarize the research or training (live tissue) completed that year, as requested in each section of the respective templates. A protocol final report is required by both the SA IRB and IACUC. The purpose of the final report is to summarize the research performed over the duration of the study to finalize the closure of the study.

**Project Final Reports – Close-out (Technical) Reports:**
All researchers are required to provide a Close-out Report upon completion of the study. The Close-out Report is due 90 days following study closure. Close-out Reports are submitted to the study PI’s ST Program Manager. Please note, failure to complete and submit required reports may result in missed future funding opportunities. Check with your Program Manager for the appropriate Close-out (Technical) Report format.

For select programmatic projects, a report is required to be submitted in 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 CIRS for 59 MDW Form 3039 requirements to obtain Public Affairs approval. CIRS will submit
your cleared report into DTIC. Refer to 59 MDWI 41-108 for more information.

**FOOD AND DRUG ADMINISTRATION (FDA)**

The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, as well as all medical devices. As the regulatory agency, the FDA is responsible for determining the appropriate regulatory pathway for any medical product. These pathways can be New Drug Applications (NDAs) [e.g. biologics, Investigational New Drugs (INDs), Investigative Device Exemptions (IDEs)] and medical device clearances [e.g. De Novo and Pre-Market Notification (510k)]. If a research protocol includes a new drug or device OR a drug or device already on the market is being used in a novel way then an assessment of regulatory requirements should be performed.

FDA Regulated Medical Products of Concern to the Air Force:
1. Drugs, including prescription drugs and Over-the-Counter (OTC) drugs; 2. Medical Devices, including simple items such as tongue depressors or crutches, complex technologies such as pacemakers or imaging technologies, dental devices and implants/prosthetics; 3. Biologics, including vaccines, blood and blood products, cellular/gene therapies, tissue or tissue products and allergenics, and 4. Combination Products, which are products comprised of two or more regulated components, such as a medical device and drug.

The FDA requirements for medical products research depends on how the medical product fits within the definitions above, the intended/indications for use, and the stage of the research. All PIs working on or proposing a project should contact the subject matter expert in the ST Research Cell for an evaluation of potential regulatory requirements. If the research involves an outside entity, whether it be a drug developer or other commercial interest, an academic partner or another government agency, the ST office can assist in the development of a regulatory assessment AND provide guidance for what regulations are applicable as well as how to comply with those regulations. If the research does involve other partners, please see the section below on Research Agreements for assistance in developing these relationships according to DoD and Air Force Regulations.

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

The 59 MDW/ST Office of Research and Technology Applications (ORTA) plays a key role in shaping the 59 MDW’s approach to technology transfer by developing and promoting the partnerships necessary for technology transfer (15 USC 3710). 59 MDW researchers and Principal Investigators (PIs) and their academic/industry partners see ORTA as the first stop in initiating their technology transfer efforts. Patent applications and licensing, Cooperative Research and Development Agreements (CRADAs), technology assessments, state and local technology transfer interface/awareness opportunities, and Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) programs are just a few of the areas in which ORTA is actively involved.

As representatives of 59 MDW/ST ORTA, Technology Transfer Specialists/Consultants serve as brokers, connecting the people essential for the effective transfer of technology and promoting collaborations. While technology transfer does have technical components, it is also dependent on person-to-person relationships forged inside and outside of the laboratory (i.e., Center of Excellence, department or clinic). Having a greater understanding of not only the function of the ORTA, but also of technology transfer issues in general, will make our efforts encouraging your laboratory’s participation in technology transfer much more effective.

This information is intended to provide internal and external audiences with information to determine if technology transfer is appropriate to address research and technology objectives. The processes described below apply to standard, unclassified Technology Transfer (T2) agreements. Nonstandard agreements involve classified, Military Critical Technologies, Foreign Owned Controlling Interest (FOCI), technology brokers, and Small Business Innovation.
ORTA ensures researchers make the most of collaborations with non-AF entities. ORTA promotes T2, the transfer and/or exchange of knowledge, capabilities, or technology with industry, state and local governments, academia and other federal agencies to fulfill both military needs and actual or potential public or domestic needs. Collaborative efforts by law are designed to allow sharing of material, expertise, facilities and equipment between parties, protect Intellectual Property; however, no DoD funding can go to the Collaborator but funding can be received by the DoD from Collaborators.

The ORTA promotes and provides T2 education to researchers, PIs, project/program managers, and others to help them better understand and utilize collaborative R&D and T2 opportunities available to them. Researchers should contact the 59th MDW/ST ORTA as early as possible in the process of collaborating with a non-AF entity in research that may require Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs), Education Partnership Agreements (EPAs) or other technology transfer vehicles.

To discuss technology transfer requirements, contact the 59 MDW/ST ORTA, Technology Transfer (T2), email: usaf.jbsa.59-mdw.mbx.59-mdw-st-technology-transfer-office@mail.mil, or phone: (210) 292-1019/3546.

**TYPES OF AGREEMENTS**

**Cooperative Research and Development Agreement (CRADA):**
A CRADA is a legal agreement between a federal agency, such as the 59 MDW, and one or more non-federal parties, such as private industry and academia, to collaborate on research and development. While no federal funding is authorized for a CRADA, CRADAs are a key technology transfer mechanism for removing barriers to collaboration, obtaining long-term value, protecting Intellectual Property (IP), and leveraging R&D investments by non-governmental agencies. Additionally, CRADAs can allow the transfer of funds from a non-federal entity to a federal entity. 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.

While the CRADA process will likely be the T2 mechanism for most purposes, there are other technology transfer mechanisms available depending on the situation. These include:

**Non-Disclosure Agreement (NDA):**
This protects proprietary information exchanged between parties during initial interactions and discussions between the 59 MDW and another party on specific technical areas. NDAs are considered contracts and must be formally reviewed by legal counsel and signed by the 59 MDW/CC to be enforceable. For most situations, the Trade Secret Act is sufficient safeguard as it prohibits the disclosure of various forms of confidential information including trade secrets, processes, and operations, style of work or apparatus by an employee of the United States. The Trade Secrets Act contains both civil and criminal penalties for violations.

**Memorandum of Understanding (MOU):**
This is a non-binding document signed by parties interested in pursuing a comprehensive agreement for the transfer of technology that defines specific technical areas of interest and the ground rules for interaction and discussion between the parties.

**Patent License Agreements:**
This is a grant of permission by the government for commercial use of 59 MDW developed intellectual property secured in an invention disclosure or US patent. The licensee pays negotiated maintenance fees and royalties on net sales. The U.S. Patent and Trademark Office issues a nonexclusive, nontransferable, license to practice or use of the 59 MDW developed or joint developed inventions. The PLA can be revoked if the licensee is found to not be effectively developing or maturing the technology.
Material Transfer Agreement (MTA):
An MTA is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes at no charge to the government.

Commercial Test Agreements (CTA’s):
This permits outside users from industry, universities, and other governmental agencies to conduct research using the 59 MDW’s unique experimental research equipment, facilities or other testing facility for the testing of materials, equipment, models, computer software, and other items, the government collects a fee for the use of these facilities to cover the cost of operation and supplies.

Education Partnership Agreement (EPA):
This is a formal agreement between a defense laboratory and an educational institution to transfer and/or enhance technology applications and provide technology assistance for all levels of education (pre-kindergarten and up). An EPA cannot be established to execute any specific projects, as this action requires the establishment of a CRADA.

Partnership Intermediary Agreement (PIA):
PIAs allow federal research agencies to enter into an agreement with a non-profit organization, state or local government (partnership intermediary) to assist the federal agency with its technology transfer efforts. PIAs help find outside industry/academia and inter-service/interagency mission enhancing partnerships, provide access to and assist companies in technology transfer, help small businesses, and work hard for the directorates with difficult to transfer military specific technologies.

Conferences, Symposia, Exhibits:
These represent opportunities to discuss and try to find solutions to common issues that arise in other ORTA programs’ daily implementation of Technology Transfer strategies. The team also participates in technical programs such as workshops, forums, and symposia, in order to promote collaboration with partners outside the USAF community.

Technical Assistance and Assessments:
ORTA specialists/consultants prepare application assessments for selected research and development projects in the laboratory that is engaged and, in the opinion of the laboratory personnel, may have potential commercial applications.

‘Personnel Exchange’, ‘Use of facilities’ (either at WHASC or industry/academic partner) and ‘Technical Data Exchange’ are other technology transfer mechanisms available depending on the situation.

59 MDW/ST ORTA can help you determine which is right for you. Meet with them early in your research process.

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, it must respect the proprietary rights of the co-developer. In addition, any other government agency may use the information emerging from a CRADA effort, but it must also protect the proprietary rights of the co-developer. The protection of proprietary rights gives added incentive to the co-developer for transferring the technology or research development through marketing and commercialization efforts.

Securing Intellectual Property (Why and How to File a Patent)
While conducting official duties, Air Force personnel may generate patentable ideas, processes, and inventions
that must be secured prior to disclosure to the public. This is especially true in research, development, and clinical practice. As such, Air Force personnel are directed by AFI 51-303 (paragraph 2.1.2.) to address this possibility before publicly disclosing the idea(s) or any related details, which includes publishing results of research in journals, periodicals, and abstracts for conferences. To initiate a review of potentially patentable ideas, processes, and inventions, interested individuals may submit an email with the background information to the Office of Research and Technology Applications (ORTA) who will assist in the completion and filing on the AF Form 1279 Disclosure and Recording of Invention and the accompanying AF Form 1981 Invention Evaluation which includes the inventor’s supervisor recommendation for filing a patent. Once patented, the patent will be advertised to the medical industry community for consideration of licensing. If a company licenses the patent, the company will develop the medical product or process and sell to industry and the military. The licensing and profit from sales may result in royalty payments to the inventor(s). Overall, the creation of a patent creates intrinsic value of the ideas, as a company is more likely to invest in developing and selling a product that other companies cannot develop or profit from (exclusive rights), and the government benefits from industry investing funding and providing a product quickly and affordably with minimal government investment.

**TRANSITION STRATEGIES**

**Transition Strategy(ies):** The main element of a knowledge or technology transition agreement is the transition strategy. The transition strategy is essentially a short narrative roadmap on how the results generated from the research and development project will be applied or used. The perspective used/presented should be that the research and development activity will be successful and can even state “if successful” as a caveat to applying the results and outcomes. The transition strategy should reference the starting and ending Technology or Knowledge Readiness Levels (TRL or KRL) following the guidance in 59 MDW/ST KRL/KTA TRL/TTA 10 October 2019 policy memo (Appendix B). The transition strategy should identify the population (end users) supported by the research and development effort and the operation/function mission(s) affected. Most important is to clearly define the list of deliverables that will be generated, and, as a minimum, must include a final report of the overall findings that are shared with 1) the representative(s) of the end users/customers, 2) any decision maker(s) for providing support (funding) and applying the results/fielding the capabilities (to include DHA and JPCs), ; and, 3) with other military research organizations or committees (i.e., Navy, Army, VA, CoTCCC, etc.), submitted to DTIC and/or other medical data repositories, and presented as an abstract at MHSRS or other conferences, and symposiums. This may also include submission to a peer-reviewed journal.

Other deliverables may include, but are not limited to (if applicable):

- Report for end-user representatives to answer their questions and provide recommendations for decision makers, especially for applying the information gathered/generated by the research
- A draft of a recommended treatment strategy that may be followed by an attending physician to apply the knowledge to practice, even if the proposed use is off label (must state so)
- An outline for a follow-on study, a draft study plan, or a full study proposal that addresses how to mature the state of the science of the research topic from one knowledge readiness level to the next, or that builds a sufficient case to transition the knowledge to clinical practice (revision to existing or generation of a new Clinical Practice Guideline or CPG)
- A statement of the type and number of clinical trial(s) that may be required, and the types and estimate of the number of patients that would be enrolled; can base the estimated types and numbers from similar clinical studies
- If a change of a Clinical Practice Guideline (CPG) is proposed, identify how the change will be submitted, reviewed, accepted, and published (if successful); clearly identify who the decision maker is or will be for the associated CPG.
- One transition deliverable could be the initiation of an Evidence Based Practice (EBP) review that will assess if the available knowledge (KRL) is sufficient to warrant a change in practice (a modified or new CPG, or a memo from DHA directing the application of the new or modified practice in the DoD)
• A statement that all intellectual property (knowledge) generated will be reviewed by the ORTA to determine if intellectual property warrants the submission of a patent disclosure package application to legal
• A statement that the data will be provided to a company through an established collaborative research agreement so that they can file a package with the FDA to seek a new/expanded label indication for an approved medical product or file Premarket Approval (PMA) package to the FDA to obtain clearance/approval for a new medical product (a path forward)
• One of the results (deliverables) for early research (6.2) can be an enhanced/refined knowledge/technology transition strategy or agreement (KTA/TTA) for signature.

Providing more details helps reduce the uncertainty and improves the transition potential. The key is to convey to the reviewers that the PI/researcher understands what it would take to apply the results to practice and conveys this understanding (i.e., strategy) in the project proposal/plan.

Example of poorly written transition strategy:
Transition Plan/Deliverable(s): The deliverables of the current proposal will be both academic and programmatic to improving health care in the field. The outcome of the current study will provide the foundation for initiating other studies to move the novel therapeutic being investigated towards human use and FDA approval. The academic products will be presented at high impact, military relevant scientific meetings and submitted to peer reviewed publications. Note: No mention of the Knowledge Readiness Level (KRL), how it will be increased, and from what level to what level. No mention of the end-user(s) who would benefit from this research project, what deliverables will be, how the knowledge will be provided (reports!) and applied (provided to decision makers), no references to clinical operations/processes/associated CPGs, and more. For additional details, please refer to Appendix B.

RESEARCH CONFERENCES
Before you travel:
• All presentation materials (abstract, poster, briefings slides, etc.) must be approved in accordance with 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, using the AF Form 3039. This approval process can take up to 30 days.
• Funding for conference travel, see specific conference information listed below. All funding must be approved by your chain of command.
• If travel is gifted (proffered) please refer to 59 MDWI 51-601, Management of Gifts and Grants of Tangible Property. This approval process can up to 30 days.
• Provide a copy of all materials and trip reports to 59 MDW/ST.

Military Health System Research Symposium (MHSRS)
The Military Health System Research Symposium (MHSRS) is the Tri-Service symposium that incorporates ATACCC, AFMS, and Navy Medicine Research Conference. This symposium is co-sponsored by the DMRDP and JPC 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 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, and 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 https://mhsrs.amedd.army.mil/SitePages/Home.aspx.
Research Fundamentals Workshop
The Research Fundamentals Workshop is an annual symposium sponsored and conducted by 59 MDW/ST staff. While the symposium is tailored to educating GHSE residents and Fellows, the Research Fundamentals Workshop is open to all JBSA health care professionals interested in research-related topics. This forum provides an overview of local research activities through 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 conference provides an overview of both collaborative research efforts as well as 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 or a research determination.

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):
A SOW is required for grant/cooperative agreements (assistance to academia or industry) or a contract in which the government receives a product.

Supplies and Equipment:
Investigators are required to 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. Animal and/or laboratory protocols to be supported by CIRS should have a complete costing estimate developed and coordinated with CIRS staff at each step of the proposal and protocol development process.

Information Management/Information Technology (IM/IT):
A cost estimate including a list of all required computer hardware and software with vender quotes, sources, total costs (including shipping and license fees), and any plans (if applicable for equipment) must 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 AFMRA/SG5 in coordination with the PI and requires semi-annual and annual reports from the PI.
- DMRDP funded projects: the 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 DHA. Please coordinate with 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.

**Letter of Support:**
For additional details, please refer to Appendix C.

**PROGRAM MANAGEMENT REVIEW (PMR):**
The Program Management Review (PMR) provides the Chief Scientist with programmatic (cost, schedule, performance) analysis and project scientific merit at least once a year. The PI will work with the assigned MDW/ST Program Manager throughout the duration of the research study. The PM will assist the PI with documentation needed for the PMR. The PI presents his/her project at the PMR and answers questions related to the research study. A pre-PMR is optional for the ST Office to gather correct information for the annual review.
HELPFUL TIPS AND PHONE NUMBERS
59 MDW Chief Scientist /ST Main Office: (210) 292-2097 (DSN 554)
Email: usaf.jbsa.59-mdw.mbx.59-mdw-st@mail.mil

Prior to protocol development, contact with the following individuals at the appropriate JBSA office (depending on where your research will be conducted) is encouraged for assistance in protocol design/methods, obtain protocol templates, and to review the need for agreements (e.g., data use agreements):
59 MDW Clinical Investigations and Research Support:

Attending Veterinarian (animal research) – Dr. Pedro (PJ) Rico, pedro.j.rico.civ@mail.mil, (210) 292-2771
Operations Branch Manager (animal research) – Mr. Todd Brown, todd.a.brown29.civ@mail.mil, (210) 292-7709
Chief, Core Laboratory Branch – Dr. Tom Gibbons, thomas.f.gibbons6.civ@mail.mil, (210) 292-7363
Chief, Office of Research Protocol Support – Ms. Rachel Montez, rachel.a.montez.civ@mail.mil, (210) 292-4683
Human Protections Administrator – Dr. Rocky Calcote, rocky.d.calcote.civ@mail.mil, (210) 292-5203
Clinical Research Administrator for ACUP; IACUC Chair – Dr. Anneke Bush, anneke.c.bush.civ@mail.mil, (210) 292-7295
CIP Funding (GHSE) – Mr. Paul Barnicott, paul.t.barnicott.civ@mail.mil, (210) 292-7068

To obtain current protocol forms and templates, policies, and publication/presentation clearance documents:

For protocol support:
Human subjects research: (210) 292-5819/6095
Animal research: (210) 292-4210/1927
usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil

San Antonio IRB – (210) 916-9425/2598
U.S. Army Medical Research and Material Command (USAMRMC) IRB – (301) 619-7801 (MCMR-RPI)

Tri-Service Research Laboratory (TSRL) IACUC – (210)539-7301 (711HPW-RHHD
USAISR IACUC - 210-539-9528 (MCMR-SRR)

SAMMC Protocol Office (210) 916-2598, you may email protocol documents to
usarmy.jbsa.medcom-bamc.mbx.bamc-irb@mail.mil or provide via CD.
TSRL Protocol Office: NAMRU (210) 539-7045, 711 HPW IACUC (210)539-7301
USAISR/MRMC Protocol Office (210) -539-4366

Research/Protocol Compliance Office POCs:
59 MDW Clinical Investigations and Research Support Quality Assurance (QA)/Quality Improvement (QI) POC: (210) 292-5146
SAMMC QA/QI POC: (210) 916-2000 or (210)916-9425
USAISR/ TSRL QA/QI POC: (210) 539-4366
U.S. Army Medical Research and Material Command (USAMRMC) QA/QI POC: (301) 619-7550 (DSN 343)

59 MDW ST Technology Transfer Office (ORTA), email: usaf.jbsa.59-mdw.mbx.59-mdw-st-technology-transfer-office@mail.mil
HELPFUL WEB LINKS


59 MDW Science & Technology- AFMS Knowledge Exchange Homepage (CAC)

59 MDW Science & Technology – 59 MDW SharePoint page (CAC)

59 MDW Science & Technology-public webpage
https://www.59 MDW.af.mil/Units/Chief-Scientist-ST/

59 MDW HRPP Operating Instructions (CAC)
https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/Human-Research-Protection-Program-Operating-Instructions.aspx

59 MDW HRPP- public webpage

59 MDW ACUP (CAC)

59 MDW Publications and Presentations Clearance Resources (CAC)

59 MDW Clinical Investigations and Research Support- AFMS Knowledge Exchange Homepage (CAC)

BAMC’s SA IRB website (outside of BAMC use Internet Explorer)

EIRB (electronic Institutional Review Board)
https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/EIRB.aspx

59 MDW SCIENCE AND TECHNOLOGY ORGANIZATIONAL MAILBOXES
59 MDW Mailbox 59 MDW ST
usaf.jbsa.59-mdw.mbx.59-mdw-st@mail.mil
59 MDW Mailbox Chief Scientist HRPP
usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil
59 MDW Mailbox Wing Clinical Research
usaf.jbsa.59-mdw.mbx.wing-clinical-research@mail.mil
59 MDW Mailbox Wing CIRS Protocol
usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil
59 MDW Mailbox CIRS Publications and Presentations
usaf.jbsa.59-mdw.mbx.crd-publications-and-presentations@mail.mil
59 MDW Mailbox 59 MDW ST Technology Transfer Office
usaf.jbsa.59-mdw.mbx.59-mdw-st-technology-transfer-office@mail.mil
FEEDBACK SURVEY LINKS
59 MDW ST Customer Feedback Survey (2019)  
https://www.surveymonkey.com/r/ZZPW7Y5

59 MDW HRPP/COI Newcomer’s Feedback Survey  
https://www.surveymonkey.com/r/Z3NBXLZ

59 MDW Office of Clinical Research Support  
https://www.surveymonkey.com/r/K2YVFSV
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>59 MDW</td>
<td>59th Medical Wing</td>
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<tr>
<td>AALAS</td>
<td>American Association for Laboratory Animal Science</td>
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<tr>
<td>AAALACi</td>
<td>AAALAC International</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>AFMRA</td>
<td>Air Force Medical Readiness Agency</td>
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<td>AI</td>
<td>Associate Investigator</td>
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<tr>
<td>AIO</td>
<td>Alternate Institutional Official</td>
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<tr>
<td>AV</td>
<td>Attending Veterinarian</td>
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<td>BAA</td>
<td>Broad Area Announcement</td>
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<td>BAMC</td>
<td>Brooke Army Medical Center</td>
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<td>CDMRP</td>
<td>Congressional Directed Medical Research Program</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CIRS</td>
<td>Clinical Investigations Research Support</td>
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<td>CITI</td>
<td>Collaborative Institutional Training Initiative</td>
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<td>CIP</td>
<td>Clinical Investigation Program</td>
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<td>CLAR</td>
<td>Component Level Administrative Review</td>
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<td>COI</td>
<td>Conflict of Interest</td>
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<tr>
<td>COR</td>
<td>Contracting Officer Representative</td>
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<tr>
<td>CPG</td>
<td>Clinical Practice Guide</td>
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<td>CRADA</td>
<td>Cooperative Research and Development Agreement</td>
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<td>CIRS</td>
<td>Clinical Investigation and Research Support</td>
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<td>DCI</td>
<td>Department of Clinical Research</td>
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<td>DHA ORP</td>
<td>Defense Health Agency Office of Research Protections</td>
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<td>DHP</td>
<td>Defense Health Program</td>
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<tr>
<td>DMLSS</td>
<td>Defense Medical Logistics Supply System</td>
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<td>DMRDP</td>
<td>Defense Medical Research and Development Program</td>
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<td>DSMB</td>
<td>Data Safety Monitoring Board</td>
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<td>DTIC</td>
<td>Defense Technical Information Center</td>
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<td>DUA</td>
<td>Data Use Agreement</td>
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<td>EDO</td>
<td>Exempt Determination Official</td>
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<td>EIRB</td>
<td>Electronic Institutional Review Board</td>
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<td>FAD</td>
<td>Funding Authorization Document</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<td>Graduate Health Sciences Education</td>
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<td>GME</td>
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<td>Humanitarian Use Device</td>
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<td>Institutional Animal Care and Use Committee</td>
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<tr>
<td>IRB</td>
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<td>U.S. Army Institute of Surgical Research</td>
</tr>
<tr>
<td>JPC</td>
<td>Joint Program Committee</td>
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<tr>
<td>MPPG</td>
<td>Medical Planning and Programming Guidance</td>
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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 that 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 or animals (as applicable).

Belmont Report: The Belmont Report consists of three basic ethical principles as a basic justification for human subjects’ research 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 to participate as a research subject.

Conflict of Interest: Any known interest, actual or potential, financial or non-financial, of a person (or of their spouse, dependent child, family member) that could affect, or could reasonably appear to affect, his/her judgment. Conflicts of interest often arise from financial relationships with a research sponsor or from intellectual property rights.

Exempt Research: When referring to human subjects 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. Eight (8) 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. When referring to animal research, exempt research involves the use of animal parts or byproducts, and is therefore exempt from IACUC oversight.

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

Financial Conflict of Interest: Equity holdings in commercial sponsors, consulting fees, royalties, patent rights, honoraria, funding incentives for patient enrollment, stock options in commercial sponsors, referral or finder's fees, nonmonetary perks or rewards, post-study reward (e.g., vacation trip), etc.

International Conference on Harmonization: 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.
APPENDIX A

Collaborative Institutional Training Initiative (CITI) Training

Each PI who submits a human research protocol and/or an exempt research protocol requiring a Limited IRB Review to the SA IRB, is required to complete role-based CITI training in human research subject protection, commensurate with their duties and responsibilities, as set forth by OUSD (P&R) standards (e.g., previously OASD(R&E) Memorandum entitled, “Minimum Education Requirements for DoD Personnel Involved in Human Research Protection,” (MERF), August 16, 2012). Associate Investigators (AI), other investigators, research project directors/coordinators/or assistants, and medical monitors listed on the protocol must also complete this training. The SA IRB administrative support staff must receive documentation of completed PI and research staff training before the SA IRB reviews the protocol. Documentation of training for AIs and other individuals must be received before final approval of the study is granted. This is one of several ways that the SA IRB ensures that investigators possess the appropriate knowledge and skills required to conduct a human research protocol. Instructions for accessing and completing CITI training are provided below, and can also be accessed at https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/CITI-Training.aspx.

Individuals with a current Component or MTF CITI training certificate are considered compliant with OUSD(P&R) CITI training requirements until such time as their current CITI training lapses. At that time, or at any time prior to the lapse of their current CITI training, the individuals shall migrate from their former Component curriculum to the OUSD (P&R) curriculum within CITI.

These have to access and complete the OUSD (P&R) CITI Courses, follow these steps:

1. Go to the CITI website [https://www.citiprogram.org] to access the training courses.
2. Register as a new user OR enter your Username and Password if you previously registered for a CITI account. New users should select "Office of the Undersecretary of Defense (Personnel and Readiness)" from the Participating Institutions drop-down menu and then complete the remainder of the registration process (e.g., username, password, name, e-mail address, etc.). Existing users will need to "Add Affiliation" and select "Office of the Undersecretary of Defense (Personnel and Readiness)" from the Participating Institutions.

You will receive a list of questions to assess your role on the study team, which will determine the training modules you will need to complete.

Question 1: Select the group appropriate to your research activities:
   - If you are an Investigator (PI and AIs): select "Biomedical Investigators and Research Study Team" if you are doing a clinical trial. AND/OR Select "Social and Behavioral Investigators and Research Study Team" if your study is Social Behavioral in nature.
   - If you are a Research Coordinator select "Biomedical Research Support Staff", "Social and Behavioral Research Support Staff", "Biomed Research Coordinators, Clinical Coordinator, Study Coordinators & Research Administrators", "SBE Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators"
   - If you are a Research Monitor additionally select "Research Monitors, Ombudsman, Subject Advocates & DSMBs"
   - If you are an HPA, select "Advisors to the Institutional Official", "Regulatory Oversight of Extramural Research"
   - If you are a Deputy or Alternate Institutional Official, select "Senior DoD Component Leadership and Institutional Officials Group", "Regulatory Oversight of Extramural Research"
Question 2: Laboratory Animal Welfare. Complete only if your study involves animals.

Question 3: Please select the Good Clinical Practice course that you would like to review. Only required for Principal Investigators on an FDA regulated study.

Question 4: Please select if you would like to complete the Responsible Conduct of Research Course. All Investigators (PI and AIs) and technical writers' are required to complete this section.

Question 5: Biosafety/Biosecurity: Only required if you are doing research with biological agents or physically handling biological specimens for your research project. *If you are physically handling blood specimens for research, please select: "OSHA Blood borne Pathogens", "Personal Protective Equipment".

3. Hit “Submit” and the courses will show under “Courses Ready to Begin”. If you started any courses and have modules to complete they will be under active courses. Completed courses are at the bottom.

4. 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 LESS THAN 80% on any module or on the overall score, you will be required to retake any failed training modules.

5. After you complete the training, download the course transcript. Copies of your completed transcript will need to be sent to the BAMC Department of Clinical Investigations (DCI) with your protocol submission. The BAMC DCI Office will not have visibility of training taken under the OUSD (P&R) CITI training account.

6. OUSD(P&R) CITI training is valid for three (3) years from the initial training date and must be re-taken in its entirety prior to the 3-year expiration date. If an investigator's CITI training expires, they must be removed from the research study until the training is re-accomplished. If the PI's CITI training expires, the SA IRB may make a determination to suspend the research until the PI re-accomplishes the training. The SA IRB may not approve a Continuing Review (Progress) Report or amendment to a study if the PI's CITI training is not current. If a request is made to change the PI for a study, the SA IRB may not approve the change, if the new PI does not have current CITI or OUSD (P&R) CITI training. There is no refresher option. Contact the 59 MDW Office of Clinical Research Support for CITI training questions at: [usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.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

1. Go to https://www.aalaslearninglibrary.org
2. Click SUBSCRIBE
3. Access Code: Were you provided an access code by an institution already subscribed to the AALAS Learning Library? Click YES.
4. Access Code: In box “Enter your Access Code” enter 2317159MDW59CRD. Click Submit.
5. Complete all requested information for Sign Up. Click Submit.
6. This should bring you to the homepage, click on your name at the top right and complete your profile with the required information. [NOTE: The system will not let you take a course until you complete your user profile.]
7. From the menu on the left side, click on Libraries.
8. Then click Animal Care and Use Courses [Here you will select the initial courses to take as part of the protocol submission process. Initial training remains current for THREE YEARS.]
9. Initial course #1: click on Anesthesia, Analgesia, and Surgery, then 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, (under the Animal Care and Use Courses section), click LATG Courses: 2016 LATG Training Manual, then click LATG 07: Occupational Health and Safety (2016) and complete each course lesson and the course exam.
11. Initial course#3: from the menu on the left side, (under the Animal Care and Use Courses section), ALAT Courses: 2018 ALAT Training Manual, click on the course required for the species used per the protocol and complete each course lesson and the course exam.
12. Initial course #4 click on Compliance and IACUC Training in the drop down menu select “Working with the IACUC”, complete each course lesson and course exam.

After the three-year initial training period, the following refresher courses are required:
From the menu on the left side, click on Libraries.

1. Refresher course #1 from the menu on the left side, (under the Research Ethics section), click Bioethics, then click Ethical Decision-Making in Animal Research and complete each course lesson and the course exam.
2. Refresher course #2 from the menu on the left side, (under the Research Ethics section), click on Responsible Conduct of Research, then click “Avoiding Financial Conflict of Interest in Federal Research” and complete each course lesson and the course exam.

APPENDIX B

MEMORANDUM FOR ALL ST STAFF

FROM: 59 MDW/ST

SUBJECT: Knowledge Readiness Level (KRL) and Knowledge Transition Agreement (KTA) Policy (supersedes 59 MDW/ST policy letter 2017-04)

1. To improve our ability to transition the outcomes of our knowledge-based research projects to the clinical, readiness, and operational missions and better address Defense Health Agency (DHA) Procedural Instruction (PI) 3200.01 Research and Development (R&D) Enterprise Activity (9 Aug 2019), we are revising our policy for the development and use of knowledge transition agreements and the use of a revised readiness scale for assessing the maturity of knowledge-based projects/products for achieving effective completion and application. If the creation of a knowledge-based product is associated with the development of a materiel solution, the AFMS Technology Transition Agreement (TTA) process and the DoD Technology Readiness Level (TRL) chart (Table E-1 of the DoD Technology Readiness Assessment Guidebook, July 2009) will be used to manage and assess overall project maturity. The primary purpose for creating a knowledge transition agreement is to convey to all stakeholders, but specifically decision makers representing the intended user(s) of the knowledge product, what the expected outcome (deliverables) will be, how they will be generated, how long this process will take, and how the results are expected to be applied to the mission. If there are any disagreements on these points, the knowledge transition agreement will be revised. The objectives for using knowledge transition processes is to help focus precious Military Health System (MHS) medical research funding on:

   a. Closing the gaps between research and practice

   b. Optimizing health outcomes and care for the Warfighter and dependents/beneficiaries

   c. Accelerating adoption of evidence-based practices

   d. Streamlining health care processes and procedures

   e. Reducing health care costs

2. Knowledge Transition Agreement (KTA): These agreements are established between the principal investigator (PI) of the research or equivalent and a designated transition partner who not only represents the intended user(s) of the knowledge which will be generated from the research, but has the decision authority to apply the knowledge product to a military mission (operational, clinical, education/training, or research). The KTA is quad-chart based to capture

   Warrior Medics – Mission Ready – Patient Focused

ST Policy Letter: OCT 10 2019
Supersedes: Ltr 2017-04, dated 2 Nov 2017
the basic information of the research that is being performed, who is performing the research, who the end-user(s) is (are), the schedule for key events, the expected outcomes of the research (deliverables), and other important information that ensures all stakeholders are adequately informed. KTAs will be developed for all extramurally funded research and projects designated by 59 MDW research directors. The use of a KTA ensures the proposed research has clearly established end-states for transitioning the results that are supported by a senior end-user representatives who will apply the knowledge generated to effect a change in a process, policy, clinical practice guideline, or even as an impetus for developing a follow-on research study (proposal) if the research is successful. Approved KTAs will be reviewed at least annually, revised as necessary, and annotated with the date reviewed (“Current as of: ______”).

3. Knowledge Readiness Level (KRL): the readiness levels of medical knowledge-based research are a method for identifying and reporting the current and projected maturity level of the state-of-the science for the medical research topic area that is being researched. The KRL chart in attachment 2 was developed by U.S. Army Medical Research & Development Command (USAMRDC) to identify to program managers and decision makers how much the proposed research will advance the knowledge of medical research topic area. Unlike a TRL, the KRL is not associated with the status or maturity of a project, as a knowledge-based research project that informs/enables another research effort may be successfully completed at a low KRL and never reach a KRL of 8 or 9 (implemented into practice).

4. For internal tracking, sharing, and reporting of the maturity level of a research project internally to the 59 MDW, the attached Project Readiness Level (PRL) may be used. The PRL is a method for identifying issues that are impacting the project schedule and reporting to key stakeholders for assistance and support. The categories in the attached KRL chart are intended to be broad-based and allow the chart to be applied to various types of research projects.

5. If you have any questions, please contact Dr. Scott Walter scott.f.walter.civ@mail.mil or (201) 292-7210.

DEBRA M. NIEMEYER, Ph.D., DAF
Chief Scientist, 59th Medical Wing

3 Attachments:
1. Knowledge Transition Agreement (KTA) Template
2. USAMRDC Knowledge Readiness Level (KRL) Chart
3. Project Readiness Level (PRL) Chart
Knowledge Transition Agreement (KTA)

Knowledge Project or Product Name

Type of Research Effort

Research Study Description: Briefly explain the nature of the situation(s) that will be researched and the knowledge gaps that exist for the (clinical, training, education, or other)

Potential Impact: Briefly explain the impact of the knowledge gained to the military missions

Deliverables: List all deliverables that will be generated by the successful completion of this project

Performers/Role:
• 59 MDW (who is leading the study)
• List any/all collaborators

Status & Key Events:
CY2X: define first phase/year events
CY2X: define second phase/year events
CY2X: define third phase/year events & conclusion

End Users:
List specific teams, missions, units, and/or organizations that will use/benefit from/be affected by this research

1. Requirements: AFMS ICL, Integrated Capabilities Document (ICD), Research Development Document (RDD), user memo (date signed/who, or other established end-user gap, requirement, desire, or request)

2. Maturity:
• Current KRL (Data):
• Next scheduled MS: Pre-MDD
• Expected completion date:

3. IRB/IRACUC (YN): N - must explain

4. Transition Partner: (name & organization)

Date KTA accepted: Month & Year

5. Clinical Trial? (YN): (N - must explain)

Budget: $K / DHP / Other / UF

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Integrity - Service - Excellence

Current as of: __________________________

Attachment 2: USAMRDC Knowledge Readiness Level (KRL) Chart

KRL 9
Research which replicates or reviews well-designed KRL 7 and KRL 8 studies. Examples include: cost analyses to achieve desired effect; comparative effectiveness studies to aid context-specific policy development or intervention decisions; systematic reviews to estimate effect size with average participants in a real world context; and post-implementation surveillance. KRL 9 research assesses "Does the application work?" in a specific context, or they may determine for which participants or time period the application works within an identified context.

KRL 8
Research which expands on or replicates KRL 7 studies to directly assess "Does the application work in the context of interest?" It uses valid designs with emphasis on external validity (generalizability) for an intended context. Example methods include: multi-site to obtain average effects; generalizable analyses of real world (e.g., administrative) data; usual or standard care (not placebo or control time) controls; and average (not ideal) participants.

KRL 7
Research which comprises early studies adapting applications supported by KRL 4-6 research for use in a military health context. Examples include: adaptation from a longer screener, feasibility and standardization for post-deployment use of a brief screener; initial multi-modal tests of combined KRL 4-6 supported interventions to achieve improved outcomes in primary care; adaptation and initial study in military mental health settings of KRL 4-6 supported therapy for PTSD; adaption and initial study of KRL 4-6 supported protective gear for preventing TBI during deployment.

KRL 6
Research which replicates well-designed KRL 5 studies. It adds nuance to answers from completed studies (e.g. not just "Can it work" and "How," but also "For Whom," "Under what conditions," or "With what frequency?"). It validates hypothesis that may suggest important application contexts (e.g. battlefield, primary care, emergency rooms, post-deployment screening). It includes systematic reviews of KRL 4 and KRL 5 studies to address "Can it work?" and "How?" questions.

KRL 5
Research which tests a priori (prespecified) hypotheses using rigorous scientific designs (e.g., RCTs for intervention efficacy) to directly assess "Can it work" and "If so, how?" It expands on or replicates a KRL 4 finding and/or improves on the design of one or more KRL 4 studies.

KRL 4
Research which generates initial knowledge regarding a human health-related application or use. KRL 4 findings require subsequent replication. Examples may include descriptive human epidemiology or preliminary human studies, human studies that test a clinical hypothesis, pilot tests of an intervention, screening or diagnostic tool, and development of instrumentation needed to test an intended application (e.g., outcome measure).
KRL 1
Research which generates initial or very early scientific knowledge without regard to or indication of a specific health use. Its purpose is inferential, with the intention to generalize. Its findings require replication. Examples include descriptive animal studies, or those that are hypothesis generating rather than hypothesis testing.

KRL 2
Research which expands on or replicates a KRL 1 finding, including systemic review of KRL 1 studies to formulate a theoretical model. Examples include animal studies that test a hypothesis or are the first true experiment on a nascent theory and human studies not based on animal study findings that are descriptive or hypothesis generating.

KRL 3
Research which validates hypothesis and hints at future applications (e.g., a tool for prediction, prognosis, screening, diagnosis, treatment, prevention). Its purpose is inferential (i.e., intention to generalize). Examples include research that replicates or systemically reviews well-designed KRL 1-2 studies or theory, descriptive studies, particularly those involving animal research.

KRL 1 – 3: Foundations
### Figure E-1. TRLs in the Medical Materiel Regulatory Process

Note for Figure E-1: The TRL descriptions are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. The S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished, particularly with regard to TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.
| PRL 1 | Initial approval of a topic or proposal that confirms a gap in knowledge exists that if answered, would enable generation of new or changes to existing clinical practice guidelines, guidance, health care standards, processes, study plan, or other knowledge-based product(s) for application to DoD mission (operational, clinical, training/educational). Changes may be considered optimization of existing processes or development of new ones to enhance operations. |
| PRL 2 | Initial launch of study, funding on contract, IRB/IACUC approvals completed (as needed), CRADAs (or other agreements) established, recruitment initiated. |
| PRL 3 | Active analytical and laboratory studies ongoing, data being actively collected, over 20 percent of planned data completed. |
| PRL 4 | Active analytical and laboratory studies ongoing, data being actively collected, over 40 percent of planned data completed. |
| PRL 5 | Active analytical and laboratory studies ongoing, data being actively collected, over 60 percent of planned data completed. |
| PRL 6 | Active analytical and laboratory studies ongoing, data being actively collected, over 80 percent of planned data collected begin validating initial observations of a data and information; |
| PRL 7 | Over 100 percent of planned data collected, IRB/IACUC closed (as appropriate), active data analyses ongoing and correlations noted; need for additional samples may reduce KRL; draft solutions and early results are presented to peers and end-users for review and heading check. Knowledge product must pass any developmental testing required. Solutions demonstrate efficacy (internal validity) and safety. |
| PRL 8 | Initial analyses indicates data and solutions are sufficient to close the knowledge gap (achieve acceptable level of significance); draft knowledge products (refined solutions) are shared with end-users and knowledge transition partner representatives (as appropriate), and feedback used to refine for finalization and consideration of implementation. Knowledge product must pass any operational testing required. If appropriate, a package for the knowledge product is submitted to the FDA. |
| PRL 9 | Knowledge products identified in the research study plan or KTA are delivered to the designated transition partner (e.g.: new/revised clinical practice guidelines, draft policy guidance memo, revised processes, a research study plan, or other knowledge-based product(s) for application to the DoD mission (operational, clinical, and/or training/educational). Draft articles are submitted to peer-reviewed literature or as abstracts to conferences for presentation as appropriate. The knowledge product submitted to the FDA is approved (if appropriate). |
MEMORANDUM FOR “(name of program agency)”
FROM: 59MDW/ST

SUBJECT: Letter of organizational support for “(Collaborator organization)” for the project entitled “(project title)” being submitted to the “(funding agency)” solicitation number “(solicitation number)”.

1. I enthusiastically support the research proposal, “(project title)” to be conducted at JBSA-Lackland. The research activities consist of “(brief project summary of activities)”. The long-term objective of this study will be “(objective)”. An important translational aspect for the US Air Force and DoD in general would be “(benefits to the Air Force and DoD)”.

2. As the 59th Medical Wing Chief Scientist, my role is to facilitate clinical and translational research, such as your work, which will address military needs and improve military care with the potential for technology transfer to the civilian sector.

3. You have my complete and enthusiastic support for this research proposal. ST staff will provide research support including lab space for the duration of the study, and in preparing presentations for scientific meetings and manuscript submission to peer-reviewed journals.

4. I look forward to assisting in any way and working closely with you and your team on this important study. This memo conveys our intent to work with “(collaborator organization)”, but does not constitute a promise of funding. If there are any questions, please do not hesitate to contact my point of contact, “(DoD PI)” at (210) 292-XXXX (office) or by email at: XXXX.eiv@mail.mil.

DEBRA M. NIEMEYER, Ph.D., DAF
Chief Scientist, 59th Medical Wing

EXAMPLE only; the letter is tailored to each submission

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