



59th Medical Wing



Grantsmanship for Clinical Research

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September 12, 2019

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Grantsmanship for Clinical Research



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Planning Your Project

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Grant writing is an important part of your professional growth strategy. It should become a long-range plan for your professional growth and development:

- Build individual credentials
- Build a track record of funding
- Work on teams with more experienced researchers
- Develop a plan for long-range, personal development

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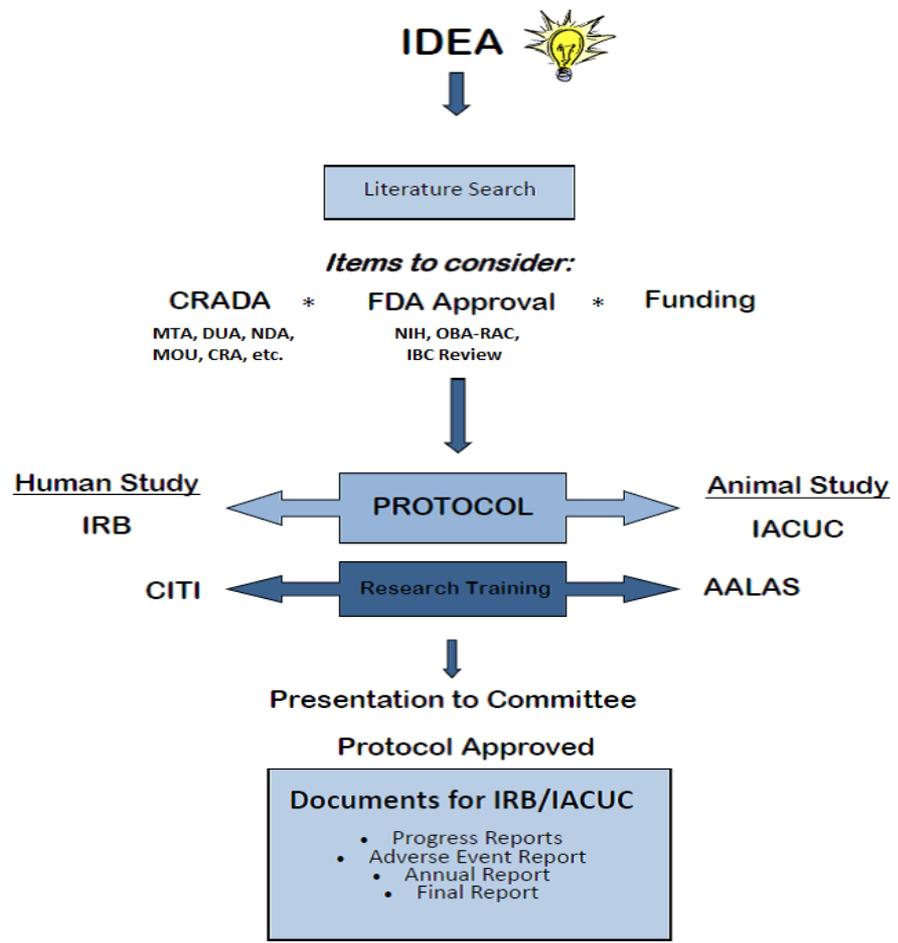
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Start with an Idea



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Research Presentations/Publications

Must have PA approval – Form 3039



Start with an Idea



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TABLE 2.1 FINER CRITERIA FOR A GOOD RESEARCH QUESTION AND STUDY PLAN

Feasible

- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope
- Fundable

Interesting

- Getting the answer intrigues the investigator and her colleagues

Novel

- Provides new findings
- Confirms, refutes, or extends previous findings
- May lead to innovations in concepts of health and disease, medical practice, or methodologies for research

Ethical

- A study that the institutional review board will approve

Relevant

- Likely to have significant impacts on scientific knowledge, clinical practice, or health policy
- May influence directions of future research

Hulley et al, Designing Clinical Research, 4th Edition, 2013



Planning Your Project



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Start with your great idea



Translate it into a project

- What will your outputs be?
- How long will it take?
- What will your approach be?
- What have you done so far?
- How will the outcomes advance DoD program goals and DoD mission?

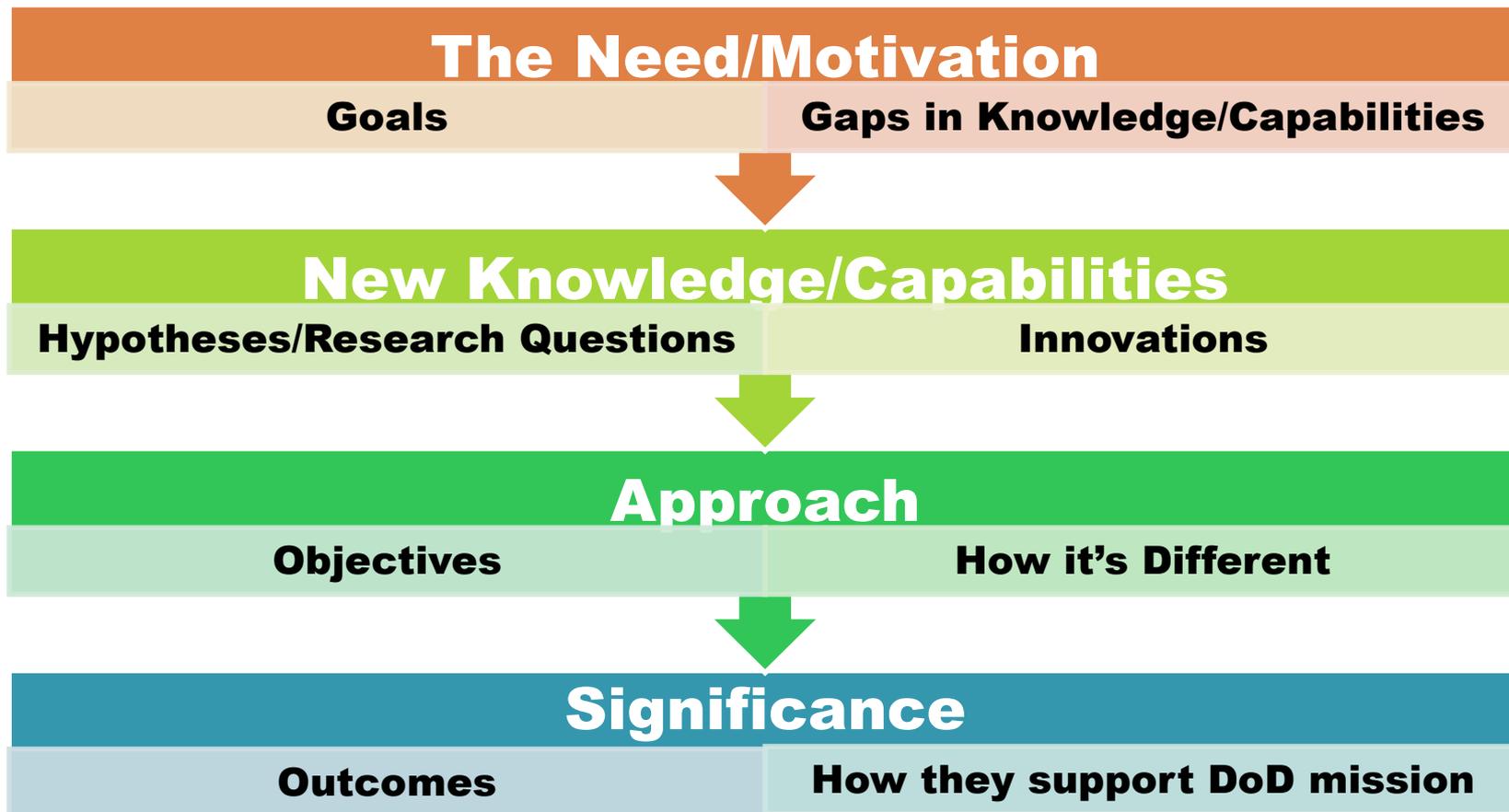


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Transition Clinical Needs to Viable Research Questions



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Match Your Question to Funding Calls



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What are you looking for?

- Funding Source (AF, joint, civilian)
- Appropriate Funding Opportunities (intramural vs extramural)
- Relevant Program Announcements
- Type of Funding to Seek: 6.1, 6.2, or 6.3



What is the Anticipated Impact?



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- Advance knowledge
- Impact clinical management
- Impact health policy
- Guide future research
 - Pilot study
 - Confirm clinical question
- Meet military requirements





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Basics of Grantsmanship

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Approach to Grant Writing



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- **FOLLOW DIRECTIONS CAREFULLY!**
- Meet your deadline; be prepared to submit 2 days prior (don't forget to route internally)
- If you are going to need letters of support, start working on those TODAY
- Excessive length; sometimes more is not better, it is simply more



Grant Proposal Planning



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Most Funding Calls will require 12 critical elements:

1. Abstract
2. Background
3. Military Relevance
4. Technical Program Summary/Methods
5. References
6. Milestones/Deliverables
7. Facilities/Equipment/Experience
8. Subcontracts
9. Cost proposal
10. Biosketch of Investigator and Co-Investigator
11. Letter of support
12. Quad Chart

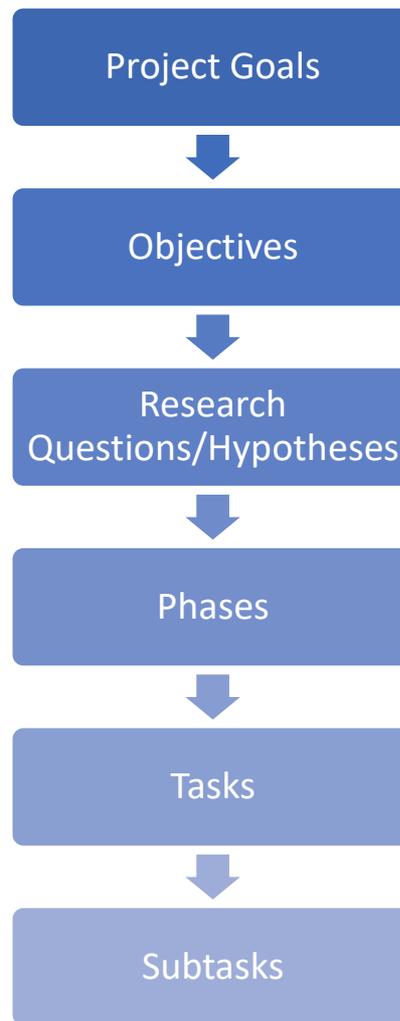


Components of a Successful Grant



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**Have A Clear
Structure**





A Path to Funding



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White Paper or Pre-Proposal

← 2-3 pages; depends on call;
needs overall budget estimate

↓
Review

← Denial

← Invitation to Write Full Proposal

↓
Full Proposal

↓
Review

← Denial

← Receive
Questions/Comments from
Reviewers

↓
Improved Full Proposal

↓
Acceptance of Proposal Letter!

↓
Congrats

← Denial

← Request Comments
from Reviewers

↓
Funded Proposal

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Funding Opportunities



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SEARCH: Grant Opportunities [v] Enter Keyword... **GO**

HOME | LEARN GRANTS | **SEARCH GRANTS** | APPLICANTS | GRANTORS | SYSTEM-TO-SYSTEM | FORMS | OUTREACH | SUPPORT

GRANTS.GOV > Search Grants

SEARCH GRANTS

BASIC SEARCH CRITERIA:

Keyword(s):

Funding Opportunity Number:

CFDA Number:

OPPORTUNITY STATUS:

Posted (20)

Closed (9)

Archived (153)

▼ FUNDING INSTRUMENT TYPE:

All Funding Instruments

Cooperative Agreement (11)

Grant (16)

Procurement Contract (1)

▼ ELIGIBILITY:

All Eligibilities

City or township governments (8)

County governments (8)

For profit organizations other than small businesses (8)

Independent school districts (0)

▼ CATEGORY:

All Categories

Consumer Protection (1)

Education (3)

Environment (2)

Food and Nutrition (3)

▼ AGENCY:

All Agencies

All Agency for International Development (2)

All Department of Defense (7)

All Department of Health and Human Services (11)

SORT BY: Relevance (Descending) [v] DATE RANGE: All Available [v]

1 - 20 OF 20 MATCHING RESULTS:

Funding Opportunity Number	Opportunity Title	Agency	Posted Date	Close Date
PA-13-255	Aging Studies in the Pulmonary System (R01)	National Institutes of Health	07/01/2013	09/07/2016
PAR-12-259	Lymphatics in Health and Disease in the Digestive, Urinary, Cardiovascular and Pulmonary Systems (R01)	National Institutes of Health	08/08/2012	09/07/2015
RFA-HL-16-007	T32 Training Program for Institutions That Promote Diversity (T32)	National Institutes of Health	11/13/2014	09/18/2017
PA-14-114	Behavioral Interventions to Address Multiple Chronic Health Conditions in Primary Care (R01)	National Institutes of Health	02/24/2014	05/07/2017
PA-12-134	Environmental Exposures and Health: Exploration of Non-Traditional Settings, (R21)	National Institutes of Health	03/23/2012	01/07/2016
PA-12-133	Environmental Exposures and Health: Exploration of Non-Traditional Settings, (R01)	National Institutes of Health	03/23/2012	01/07/2016
RFA-HL-16-006	Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research (K01)	National Institutes of Health	11/25/2014	11/17/2017
PA-14-350	Studies in Neonatal and Pediatric Resuscitation (R01)	National Institutes of Health	09/25/2014	01/07/2018
RFA-HL-16-001	Molecular Imaging of the Lung - Phase 2 (R01)	National Institutes of Health	03/17/2015	06/15/2015
W81XWH-15-PRMRP-FPA	DoD Peer Reviewed Medical Focused Program Award	Dept. of the Army -- USAMRAA	04/17/2015	10/28/2015
W81XWH-15-PRMRP-DA	DoD Peer Reviewed Medical Discovery Award	Dept. of the Army -- USAMRAA	04/17/2015	07/09/2015
W81XWH-15-PRMRP-TTDA	DoD Peer Reviewed Medical Technology/Therapeutic Development Award	Dept. of the Army -- USAMRAA	04/17/2015	10/15/2015
W81XWH-15-PRMRP-IIRA	DoD Peer Reviewed Medical Investigator-Initiated Research Award	Dept. of the Army -- USAMRAA	04/17/2015	10/15/2015
W81XWH-15-PRMRP-CTA	DoD Peer Reviewed Medical Clinical Trial Award	Dept. of the Army -- USAMRAA	04/17/2015	10/22/2015
CDC-RFA-DD15-1507	Public Health Surveillance for the Prevention of Complications of Bleeding Disorders	Centers for Disease Control and Prevention	03/13/2015	05/20/2015
BAA-11-01-HPW	Aerospace Medicine, Clinical Research, Human Performance Research, and Expeditionary Medicine	Air Force -- Research Lab	12/16/2010	12/15/2015
RFA-674-12-000002	Systems Strengthening for Better HIV/TB Patient Outcomes	South Africa USAID- Pretoria	12/07/2011	
RFA-674-12-000005	Comprehensive District-Based Support for Better HIV/TB Patient Outcomes	South Africa USAID- Pretoria	05/04/2012	
W81XWH-USSOCOM-BAA-15-1	DOD USSOCOM Broad Agency Announcement	Dept. of the Army -- USAMRAA	04/14/2015	04/14/2016

<http://www.grants.gov/web/grants/search-grants.html>



Funding Opportunities



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CDMRP

Transforming Healthcare through Innovative and Impactful Research

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Search...

Submit

Home / Funding Opportunities / Synopsis of Current Program Funding Opportunities

Funding Opportunities



Synopsis of Current Program Funding Opportunities

- Alcohol and Substance Abuse Disorders
- Amyotrophic Lateral Sclerosis
- Autism
- Breast Cancer
- Defense Medical Research and Development Program
 - Combat Casualty Care Research Program (JPC-6)
- Lung Cancer
- Military Burn
- Neurofibromatosis
- Ovarian Cancer
- Parkinson's
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Tick-Borne Disease
- Tuberous Sclerosis Complex

<http://cdmrp.army.mil/funding/default.shtml>

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CDMRP Pre-Proposal Template



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Tab 1 – Application Information

Tab 2 – Application Contacts

Tab 3 – Collaborators and Key Personnel

Tab 4 – Conflicts of Interest

Tab 5 – Pre-application Files

Preproposal Narrative (four page limit)

Topic Area, Research Idea, Research Strategy,
Impact, Relevance to Military Health

Supporting Documentation: References, List of
Abbreviations, Acronyms & Symbols, Biosketches

Tab 6 – Submit Preproposal

Follow the Format!



Example of a Successful Grants



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Write a Compelling White Paper

- Focus on the outcomes and benefits of your research **to the funder**
- Describe the problem clearly
- Place your research in context of the state of the art
- Explain why your approach is different
- Provide a concise overview of what you will do
 - **Not “We will explore phenomenon x” – too vague**
 - **Instead, “In Task 1 we will measure x; in Task 2 we will develop y; in Task 3 we will evaluate z...”**



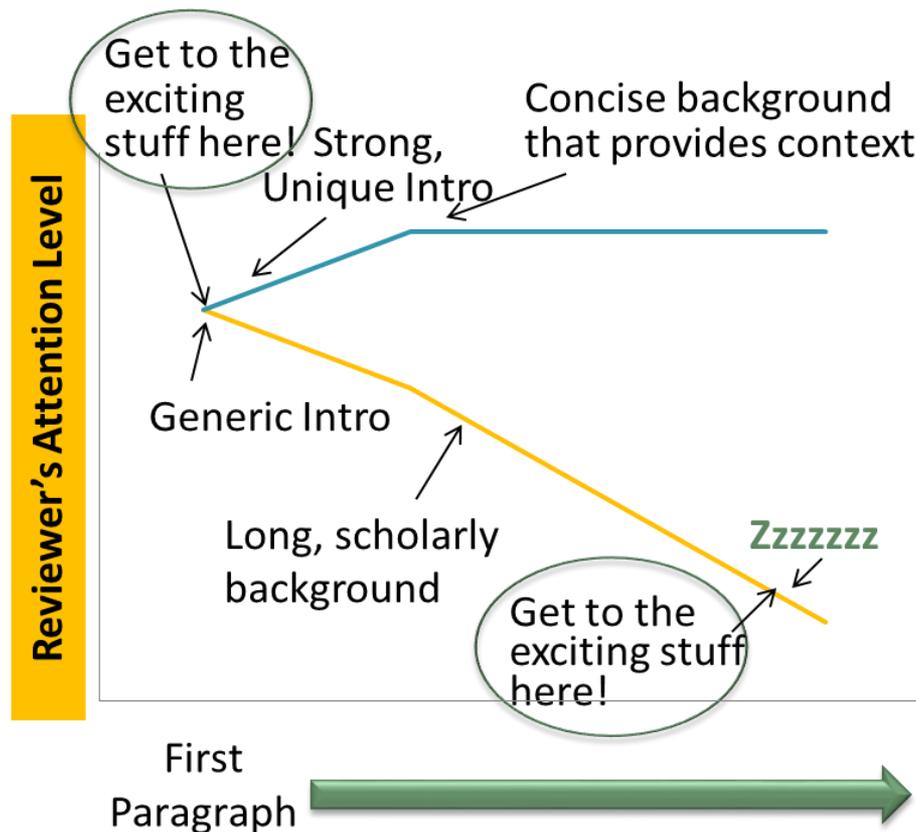
Example of a Successful Grants



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Common Mistakes to Avoid

- Keeping Reviewer Attention
- Failure to connect research to outcomes of interest to DoD
- Long, wordy academic introduction
- Vague plan
- Unclear outcomes and deliverables





Are You Making the Grade?



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Grant Grading 101

Reviewer 1st Impression

- **Did the Applicant Follow Directions?**
- **Are Specific Aims and Objectives Clear?**
- **Is the Technical Approach Feasible?**

Causes for Rejection

- **Missed Deadline**
- **Sections Missing**
- **Page Limit Exceeded**



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A Closer Look at Writing

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7 Main Proposal Sections Defined



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1. **Title:** A statement that reflects the centrality of the proposed work.
2. **Abstract:** A miniature version of the proposal. Concise. Summary of what, why, and how.
3. **Background or Introduction:** Findings that led you to propose this work.
4. **Hypothesis, Objectives:** Statements of possible conceptual or mechanistic explanation for a set of findings
5. **Overall Goal, Long-term Goal:** Descriptive statements of what you plan to achieve and would like to achieve in the future
6. **Research Approach, Plan, Strategy:** Conceptual and experimental approaches to carry out the proposed work and accomplish its stated goals.
7. **Military Relevance, Focus Area:** Importance of the proposed work for the military.

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Writing the Title



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Title Examples

Good

“Role of antibody signaling in inducing tumor dormancy”

Bad

“The in vitro anti-inflammatory effects of recombinant anti-CD25 immunotoxin on lamina propria T cells of patients with inflammatory bowel disease are not sufficient to cure experimental colitis in mice”



Writing the Abstract



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Abstract

A short narrative that captures the essentials of the proposed work.

What does it tell?

- What? Why? How?

What is it meant to do for the reader?

- To describe with great concision the essentials of the proposed work
- To make the main aspects stand out
- To briefly describe the **scientific rationale** for the proposed work
- To induce the reader to read the rest of the writing.



Writing the Introduction



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Introduction (Background)

A narrative that describes the background information relevant to the proposed work. It's not a detailed review of the field or of the subject.

What does it tell?

- What is known and relevant to the work you are proposing.
- What is unknown and relevant to the work you are proposing.



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Specific Aims/ Hypothesis

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Do's and Don'ts of Specific Aims



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- **Well-designed Aims**

- More than one possible outcome is acceptable
 - Success is not dependent on any single outcome

- **Unacceptable Aims**

- Only one possible outcome is interesting
 - Success of a subsequent aim is dependent on this outcome

- **Fatally flawed Aims**

- Descriptive, unfocused, obvious, naïve, or uninterpretable



Hypothesis

A statement of possible conceptual or mechanistic explanation for a set of findings (observations, results; yours or others’).

- Have an overarching or central hypothesis.
- Must make logical, scientific sense, at least to those in the field.
- Must have solid foundation in observations, whether empirical or theoretical.

What It Is Not

- Mere opinion, hunch, speculation
- An arcane notion that makes sense only to you and your friends
- Just an idea you feel like checking out
- An idea or notion that innumerable people have considered, think is true, but no one has ever subjected it to any rigorous, objective inquiry



Writing the Hypothesis, Objectives, Aims



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Objectives

- Subsets of the overall goal
- Typically several for a multiyear or complex project.

Specific Aims

Narrowly defined goals or objectives; subsets of the overall goal and broader objectives.

- **Dependent, Linked, Sequential:** Aim 1 → Aim 2 → Aim 3
- **Independent:** Aim 1. Aim 2. Aim 3.



Writing the Overall Goal, Long-term Goal



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Overall Goal

General statements descriptive of what you plan to achieve with this work.

- Be conservative.
- Avoid lofty statements and goals generally understood to be for the whole of mankind, e.g., “our goal is to cure cancer,” “the overall goal of this work is to develop a fool-proof test for breast cancer,” “we expect these studies to result in the best treatment modalities,” and the like.

Long-term Goal

Greater or other goals that you could achieve if you continued the work.

- Include what you think you could achieve if stayed the path with sustained funding and other requisite resources.

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Writing the Research Plan



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Research Plan, Research Approach, Research Strategy:

Detailed description of the strategies and approaches to accomplish the proposed work.

What does it tell?

- The how of the proposed work
- The why of the proposed work



Writing the Research Plan



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How do I write an effective Research Plan?

- Clearly describe the experimental approaches and techniques.
- Omit details that are truisms and commonly accepted norms.
- Provide only the directly relevant details.
- Omit extraneous details.
- Do not omit any procedural detail that would strengthen your proposal.



Responding to Reviewers



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- Reviewers typically assess concepts, strategies, approaches, techniques.
- Reviewers do not have the responsibility to improve your writing.
- Comply with general suggestions if they improve your proposal.
- Do not shift the burden of finding and correcting your writing mistakes to reviewers.



Responding to Reviewers



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- Carefully and calmly assess each critique.
- Do not rush to compose a response.
- Never compose angry responses, even if the critique appears irrelevant or unjustified.
- Logically, scientifically – but ever so politely – rebut those items that merit rebuttals.



Grant Writing: English



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- Make **grammar, punctuation, and spelling** 100 % accurate.
- Make sure **diction** is appropriate. If in doubt, double check.
- **Syntax** is crucial for writing well; improper syntax can fail to precisely convey the intended meanings, and thus create confusion.
- Organize sentences in a logical sequence and progression. Use words and phrases that logically link sentences and thoughts.
- **Bad grammar, bad spelling, bad syntax, imprecise diction** → Intended meanings not conveyed or incorrectly conveyed → Reviewer unable to understand, unable to make sound judgements → Recommends against funding, or recommends a revision → Problems not fully corrected in the resubmitted proposal → Reviewer angry, thinks the seeker is not serious → Recommends against funding → **The End**

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Summary



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- **Read the entire funding call, understand the requirements, and ensure you have sufficient time to respond.**
- **Know what you need to submit and when (White Paper vs Full Proposal, Supporting Documentation).**
- **Provide a clear, concise, and relevant white paper or proposal.**
- **Ensure your proposal is aligned with the funding agency's mission or priorities.**
- **Check your grammar, spelling, and punctuation.**
- **Seek Help Early!**

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Transition Strategy



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- Must have a clear impact on medical mission/operations
 - Improve operations/capabilities with in-garrison care, readiness, training/education, or deployed medical ops
- Proposal must clearly define:
 - The end state if project is funded and successfully completed
 - Impact/change(s) to standard of care and *potential* results
 - Cost/benefit analysis & report to managers to make fielding decisions
- Need strong transition strategy for positive results: include as deliverable(s) for next step, study, policy, etc..
- Include an end user statement from a decision making authority that they will use/implement if successful
- Include statement from company(ies) who are/may be the FDA sponsor to provide support and transition



Transition Strategy



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- Include a regulatory pathway if applicable: consult with 59 MDW FDA SME (**TBD**) for help/support
- Collaborative proposals are viewed as less risky and more likely to be supported, especially joint-services
 - Contact 59 MDW Office of Research and Technology Applications (ORTA) to establish agreements:
 - CRADA: Cooperative Research and Development Agreements
 - MTA: Material Transfer Agreement
 - ELA: Enterprise License Agreement
 - NDA: Non-Disclosure Agreement
 - JOA: Joint Operating Agreement
 - MOU/MOA: Memorandums Of Understanding/Agreement
 - Contact 59 MDW ORTA for support with intellectual property (IP) identification, protection, licensing, patents, filing



Transition Strategy -Scoring Criteria



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Transition Strategy/Plan		
Prioritization	Score	Criteria
High  Low	4	Results will be immediately applied to operational mission by combat medic
	3	Acknowledgement from central board or procuring agency decision maker that the results will be used to procure items or issue a procurement recommendation
	2	Results will transition to a service specific function for several organizations/clinics
	1	Results will be published and briefed at conferences
	0	No transition strategy, unlikely to result in any change to military equipment sets, policies, or procedures

- Must also demonstrate how results will be shared with other services, DHA, and anyone else who can benefit from the knowledge



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CDMRP Proposal Example

<https://cdmrp.army.mil/funding/prgdefault>

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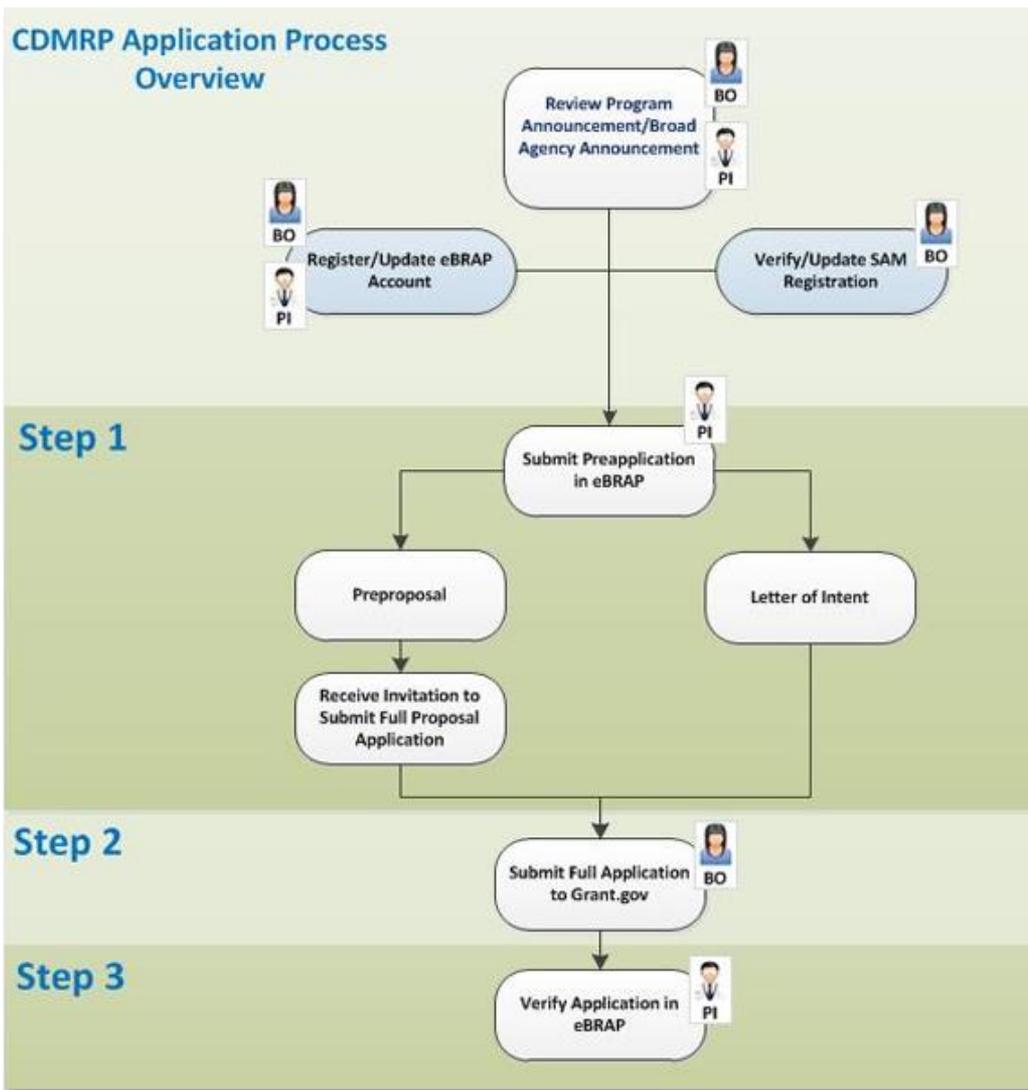
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I. OVERVIEW OF THE FUNDING OPPORTUNITY

**Intramural Funding Opportunity Announcement and Application Instructions
for the Department of Defense**

Defense Health Program

Congressionally Directed Medical Research Programs

Clinical Research Intramural Initiative

Investigator-Initiated Research Award

Funding Opportunity Number: DHA19CRIIIIRA

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), April 22, 2019
- **Invitation to Submit an Application:** June 07, 2019
- **Application Submission Deadline:** 11:59 p.m. ET, August 7, 2019
- **End of Application Verification/Approval Period:** 5:00 p.m. ET, August 14, 2019
- **Peer Review:** October 2019
- **Programmatic Review:** November 2019



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Table 1. Full Application Submission Guidelines

Application Package Location
Download application package components for DHA19CRIIIRA from eBRAP (https://ebrap.org).
Full Application Package Components
<p>Tab 1 – Summary: Provide a summary of the application information</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Resource Manager/Comptroller or equivalent Business Official.</p> <p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
Application Package Submission
<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval of Full Application: After all components are uploaded, and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will validate files against the Funding Opportunity Announcement requirements and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the application submission. eBRAP will notify your Business Official or equivalent by email to log onto eBRAP to review and approve the submission.</p>
<u>Application Verification/Approval Period</u>
<p>After eBRAP has processed the full application, the organizational Business Official or equivalent and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification/approval period, the full application package, <i>with the exception of the Project Narrative and Budget Form</i>, may be modified. Only the Business Official or equivalent can modify the application components during the verification/approval period. However, if the Business Official or equivalent selects the “Return to PI” button, the PI can update the application BUT must then resubmit the application for Business Official approval. Your Business Official or equivalent should log into eBRAP to review and to approve prior to the application verification/approval deadline.</p>



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Funding Opportunities and Forms

CDMRP

Current Funding Opportunities

Autism Research Program (ARP) 2019	click to view Award Mechanisms
Bone Marrow Failure Research Program (BMFRP) 2019	click to view Award Mechanisms
Breast Cancer Research Program (BCRP) 2019	click to view Award Mechanisms
Broad Agency Announcement (MRMC-BAA) 2019	click to view Award Mechanisms
Chronic Pain Management Research Program (CPMRP) 2019	click to view Award Mechanisms
Defense Medical Research and Development Program (DMRDP) 2019	click to view Award Mechanisms
Duchenne Muscular Dystrophy Research Program (DMDRP) 2019	click to view Award Mechanisms
Gulf War Illness Research Program (GWIRP) 2019	click to view Award Mechanisms
Hearing Restoration Research Program (HRRP) 2019	click to view Award Mechanisms
Kidney Cancer Research Program (KCRP) 2019	click to view Award Mechanisms
Lung Cancer Research Program (LCRP) 2019	click to view Award Mechanisms
Lupus Research Program (LRP) 2019	click to view Award Mechanisms
Melanoma Research Program (MRP) 2019	click to view Award Mechanisms
Multiple Sclerosis Research Program (MSRP) 2019	click to view Award Mechanisms
Peer Reviewed Cancer Research Program (PRCRP) 2019	click to view Award Mechanisms
Peer Reviewed Orthopaedic Research Program (PRORP) 2019	click to view Award Mechanisms
Prostate Cancer Research Program (PCRP) 2019	click to view Award Mechanisms
Psychological Health and Traumatic Brain Injury Research Program (PH-TBI) 2019	click to view Award Mechanisms
Reconstructive Transplant Research Program (RTR) 2019	click to view Award Mechanisms
Special Operations Command (SOCOM) 2019	click to view Award Mechanisms
Spinal Cord Injury Research Program (SCIRP) 2019	click to view Award Mechanisms
Tick-Borne Disease Research Program (TBDRP) 2019	click to view Award Mechanisms

<https://ebrap.org/eBRAP//Login.htm>

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Generic Forms for Application Submission

	MS Office	PDF
CDMRP Biographical Sketch		n/a
Quad Chart Template		n/a
Award Chart		n/a
FY19 IND/IDE Documentation Form	n/a	
Pre-application Budget Summary Form		n/a
Collaborating DoD Military Facility Budget Form	or	n/a
DoD Military Budget Form	n/a	
Common Blinding Mistakes and How to Avoid Them		
SOW (Statement of Work) Generic Format		n/a
SOW for Basic Research (Training Section optional)		n/a
SOW for Clinical Research (Including Trials, Special Populations)		n/a
SOW for Advanced Tech Development Research		n/a
SOW for Collaborative PI projects		n/a

Regulatory Information and Forms

	MS Office	PDF
Safety & Environmental Resources	n/a	n/a
Environmental Compliance Assurance		
Animal Use Guidance and Documents	n/a	n/a
Appendix for Research Involving Animals (Abbreviated Version)	n/a	n/a
Appendix for Research Involving Animals (Full Version)	n/a	n/a
Guidance for Submission of Changes to Animal Care and Use Protocols	n/a	
Adverse or Regulatory Events Requiring Reporting to ACURO	n/a	
Human Resources FAQs	n/a	n/a
Human Research Protection Office Overview	n/a	n/a
DoD Unique Information for Investigators	n/a	n/a
Guidance on HRPO Review Requirements for Research Involving the Secondary Use of Data/Specimens	n/a	
Human Subject Resource Document		
Human Research Protocol Submission Form		n/a
Research Involving the Use of Data/Specimens		n/a
Army Policy for Use of Human Cadavers	n/a	n/a
Cadaver Use Submission Form and Checklist		

<https://ebrap.org/eBRAP/public/Program.htm>

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The following steps are required to complete submission of a Full Application

Step Full Application Steps

- 1 [Contacts](#)
- 2 [Full App Files](#)
- 3 [Budget Data \(including Congressional District of Applicant\)](#)
- 4 [Submit Full Application](#)

Required Files

File	Page Limit	
Project Narrative	15	
Supporting Documentation		
Technical Abstract	1	
Lay Abstract	1	
Statement of Work	3	
Letters of Support		
Impact and Military Benefit Statement	1	
Transition Plan and Regulatory Strategy	2	
Key Personnel Form		
PI Biographical Sketch	6	
Budget Form		
Budget Justification		
Project/Performance Site Location(s) Form		

Optional Files

File	Page Limit	
Animal Research Plan		
Human Subject Recruitment and Safety Procedures		
Data Management		
DoD Military Budget Form		
PI Current & Pending Support		
Key Person Biographical Sketch	6	
Key Person Current & Pending Support		
Subaward Budget		
Subaward Budget Justification		
Budget - Additional Senior Key Persons		
Budget - Additional Equipment		
Subaward Budget - Additional Senior Key Persons		
Subaward Budget - Additional Equipment		
SFLLL or other Explanatory Documentation		
Pre-application		
Additional Performance Site Locations		
Other		



Grantsmanship for Clinical Research



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Research Team/ Budget

PEOPLE

MISSION

INNOVATION



Assembling a Strong Research Team



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Forming (*assemble team; deal with ambiguity*)

Storming (*deal with criticism; develop ideas*)

Norming (*procedures, cohesion*)

Performing (*cooperation*)

[Adjourning]

Source: Bruce Tuckman (1965) *Small Group Development*



Cooperative Agreements



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- CRADAs

- Bilateral agreements for R&D collaboration between 59 MDW & industry, academia, or nonprofit
- Federal lab can commit resources, e.g. personnel, facilities equipment, intellectual property (w/ or w/o reimbursement), but no funds to the non-federal party
- Non-federal party can commit similar resources, as well as funds

- MTAs

- Allow sharing of tangible research materials including technology, supplies, samples, etc. in one direction: from industry to 59 MDW researchers

- EPAs

- Partnership with educational institutions in the US and 59 MDW to encourage the Science, Technology, Engineering, and Mathematics (STEM) at all levels of education



Statement of Work



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STATEMENT OF WORK – Month/Day/Year
PROPOSED START DATE Aug XX, 20XX

Site 1: Research Institution Name
Address for Org#1
PI: XXXXXXXXX

Site 2: Research Institution Name
Address for Org #2
Partnering PI: YYYYYYYYYY

Specific Aim 1(specified in proposal)	Timeline	Site 1	Site 2
Major Task 1	Months		
Subtask 1	1-3	Dr. X	Dr. Y
Subtask 2	1-3	Dr. X	Dr. Y
Subtask 3	3	Dr. X	
Milestone(s) Achieved			
Local IRB/IACUC Approval	3		
Milestone Achieved: HRPO/ACURO Approval	6		
Major Task 2			
Subtask 1	1	Dr. Y	Dr. X
Subtask 2	1	Dr. Y	Dr. X
Subtask 3	2-3	Dr. Y	Dr. X
Milestone(s) Achieved:	4		Dr. X
Specific Aim 2			
Major Task 3			
Subtask 1	1	Dr. X	Dr. Y
Subtask 2	5	Dr. X	Dr. Y
Milestone(s) Achieved:	9	Dr. X	Dr. Y



Budget



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Knowledge of expenses associated with running a program is fundamental. Without this understanding grant writers will not be able to comprehend how much funds are needed to achieve the goals and objectives set for a program.

- Do Not Reuse Quotes – prices fluctuate and can impact completion of your study
- Consult with Support Entities (animal and laboratory support for appropriate costing)
- Obtain ordering/shipping information for hard to obtain items (international orders, etc.)



Budget



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DoD MILITARY FACILITY BUDGET FORM

Military Facility

Detailed Cost Estimate Form - Cumulative Budget

Make sure project end date is entered below!

Principal Investigator:

DETAILED BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT						Project Start Date:		
BUDGET CATEGORY TOTALS ¹	INITIAL BUDGET PERIOD (FROM FORM PAGE 1)	ADDITIONAL YEARS OF SUPPORT REQUESTED				TOTAL	Project End Date:	
		2nd	3rd	4th	5th			
PERSONNEL	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
FRINGE BENEFITS	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
CONSULTANT COSTS	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
MAJOR EQUIPMENT	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
MATERIALS, SUPPLIES, AND CONSUMABLES	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
TRAVEL COSTS	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
SUBJECT-RELATED COSTS	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
OTHER DIRECT COSTS	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
SUBTOTAL DIRECT COSTS (No Subcontract)	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
SUBCONTRACT COSTS	DIRECT	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
	INDIRECT	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						\$ 0		
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						\$ 0		
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT THIS AMOUNT SHOULD AGREE WITH THAT ENTERED IN THE REQUIRED FILES						\$ 0		

¹ Itemize all budget categories for each year on the Justification page that follows.

JUSTIFICATION: ITEMIZE ALL BUDGET CATEGORIES FOR EACH YEAR. FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS IN THE GENERAL SUBMISSION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.



Budget



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Attachment 1: R&D Pricing for Services at 59 MDW/STC

Note: Pricing is dependent on contract costs; they are subject to change. This price list may not be all-inclusive.

Species	Type	Cost	Additional Notes
Swine	Locally procured (farm)	\$500	
Swine	Specific pathogen-free (SPF)	Vendor's animal cost + transportation costs	Call CIRS for price estimates; species-dependent
Rat		Vendor's animal cost	Call CIRS for price estimates; species-dependent
Mouse		Vendor's animal cost	Call CIRS for price estimates; species-dependent
Sheep		Vendor's animal cost	Call CIRS for price estimates; species-dependent
Goat		Vendor's animal cost	Call CIRS for price estimates; species-dependent

Service	Cost	Additional Notes
Procedure Room Fees: 1. Large Animal 2. Small Animal	\$250/day \$40/day	Covers operating costs associated with Procedure Room equipment, instruments, anesthesia and routine surgical supplies. Does not include protocol specific items.
Surgery Room Fees: 1. Large Animal 2. Small Animal	\$500.00/day \$50/day	Covers operating costs associated with Surgical Suite equipment, instruments, anesthesia and routine surgical supplies. Does not include protocol specific items.
Veterinary and Surgical Support	\$45/hour	A protocol review will be performed and the number of hours required will be determined by the Operations Branch Supervisor. A rate of \$45/hour will be applied for the estimated hours of technician support and will be provided as a cost line in the Operations Branch Letter of Support.
Per Diem Rate – Large Animal 1. Single Run Cage 2. Double Run Cage 3. Pasture	\$10/day \$13/day \$5/day	Covers husbandry supplies

Service	Cost	Additional Notes
Per Diem Rate – Small Animal 1. Rats 2. Rabbits 3. Mice	\$0.75/day \$2.75/day \$0.75/day	Covers husbandry supplies
Molecular Manpower Support 1. Molecular Scientist 2. Bioinformatics Specialist 3. DREN Support	\$45/hr \$75/hr \$50/hr	A protocol review will be performed and the number of hours required will be determined by the Laboratory Branch Chief. The applicable rate/hour will be applied for the estimated hours of technician support and DREN usage, and will be provided as a cost line in the Laboratory Branch Letter of Support.
Bioinformatics for Genomics Research (analyst contract costs)	\$150/specimen	A cost of \$150 per specimen will be assessed for each sequence sent for bioinformatics interpretation. This is the current contract costs associated with sending molecular sequencing information to a contract Bioinformatics Service.

Supplies	Cost	Additional Notes
Protocol-specific	TBD	All protocol-specific supplies are added costs and must be identified in the protocol. All protocol-specific supplies will be ordered in DMLSS using the DMLSS Service Code associated with the protocol.



Use of CIP Funds



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DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

13 Feb 2019

MEMORANDUM FOR RECORD

FROM: 59 MDW/STC

SUBJECT: Use of CIP Funds to Support Graduate Health Sciences Education Research

1. Each year, Clinical Investigations & Research Support receives funds from the Air Force Medical Support Agency (AFMSA) to support the USAF Clinical Investigations Program (CIP) primarily at the 59th Medical Wing. To meet the requirement of Department of Defense Instruction 6000.08, *Defense Health Program Research & Clinical Investigation Programs* (January 22, 2014), the USAF CIP is specifically designed to support Graduate Health Sciences Education (GHSE) and other allied health programs of the Air Force and to promote high professional standing and accreditation of USAF health education programs. USAF CIP funds are used to procure supplies and research specific equipment for use by GHSE students. The following guidelines will be used in the evaluation of research protocols for funding.

- a. The protocol must support GHSE-required scholarly activity.
- b. The protocol must have a USAF Principal Investigator (PI) who is actively engaged in the research. The PI can be a GHE Fellow/Resident or USAF Staff or GHSE Faculty.
- c. If the PI is a USAF Staff or GHSE Faculty member, there must be a USAF GHSE Fellow(s) or resident(s) as Associate Investigator(s) (AIs) who is/are actively engaged in the research.
- d. Members of other Services may be assigned to the protocol and engaged in the research as AIs; however, there must be evidence that the primary purpose of the protocol is to support the USAF GHSE program.
- e. There must be an approved protocol and a completed budget request included as part of the supporting documentation for the protocol. Contact Dr. Anneke Bush (DSN 554-7295) to discuss funding requirements.
- f. The PI is responsible for communicating with the Clinical Investigations & Research Support staff to discuss funding issues and must report any research compliance issues immediately.
- g. In the event of termination or suspension of the protocol (e.g., for unexpected duty changes, compliance issues, etc.), the PI must notify Clinical Investigations & Research Support immediately so funding can be suspended or terminated as necessary.
- h. CIP funds are current Fiscal Year funds and must be expended before the end of the fiscal year (Sept 30). Clinical Investigations & Research Support staff will work with PIs to ensure resources can be obligated as required. It is the responsibility of the PI to provide all information necessary to acquire research supplies and equipment to the staff in a timely manner to allow for purchase of requirements.

2. All requirements as outlined above must be met before requests for funding will be considered to support GHSE research. The normal funding limit is \$30K. However, all requests for funding, regardless of requested amount, are reviewed on a case-by-case basis.

WALTERS.CAROL.C.1034 Digitally signed by
WALTERS.CAROL.C.103435653
355653 Date: 2019.02.13 12:26:46 -0600

CAROL C. WALTERS, Col, USAF, BSC
Director, Clinical Investigations and Research Support

PI: USAF Resident or Fellow

Funding Level: \$15K - \$30K

Must have approved IRB or IACUC protocol

Send approved protocol and completed budget form to:

paul.barnicott.1@us.af.mil

1		TITLE OF PROJECT:	
2	DETAILED COST ESTIMATE:	FROM	THROUGH
3	Principal Investigator (Last, first, middle init.)		
4			
5	(Detailed Budget for Year)	1st	2nd
6		3rd	4th
7		5th	6th
8	LABOR	DOLLAR AMOUNT REQUESTED	
9	Position	ROLE ON PROJECT	EST. FTE
10			\$
11			Dir. Cost
12			\$
13			\$
14			\$
15			\$
16			\$
17			\$
18			\$
19	SUBTOTALS		\$
20	CONSULTANT COSTS		\$
21	MAJOR EQUIPMENT (ITEMIZE)		\$
22			\$
23	MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)		\$
24			\$
25			\$
26	TRAVEL COSTS (FROM WORKSHEET PROVIDED)		\$
27	RESEARCH-RELATED SUBJECT COSTS		\$
28	OTHER DIRECT COSTS (ITEMIZE BY CATEGORY)		\$
29			\$
30	SUBTOTAL OF OTHER DIRECT COSTS FOR THIS BUDGET PERIOD		\$
31			\$
32			\$
33	CONSORTIUM SUBAWARD COSTS		\$
34			\$
35	INDIRECT COSTS		\$
36			\$
37	TOTAL DIRECT COSTS FOR THIS BUDGET PERIOD		\$
38	TOTAL INDIRECT COSTS FOR THIS BUDGET PERIOD		\$
39	(These funds are required if project managed by an external research foundation such as the Gates Foundation or Beazley Jackson Foundation)		\$
40			\$
41	TOTAL DIRECT AND INDIRECT COSTS FOR THIS BUDGET PERIOD		\$
42	FIXED FEE (IF APPLICABLE)		N/A
43	TOTAL COSTS AND FIXED FEE		\$
44			\$



Be Aware of Timeline Challenges



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- **Contract Actions**

- Personnel
- Direct Costs/Equipment

- **Agreements**

- CRADA
- MTA
- MOU/MOA

- **Regulatory Requirements**

- IRB
- IACUC
- FDA - IND/510K

- **Organizational**

- Accounting
- Fiscal Year Rollover
- Support Letters

- **Career**

- PCA/PCS
- Deployment

- **Logistics**

- Getting Equipment
Delivered in a
Timely Fashion



Grantsmanship for Clinical Research



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Common Mistakes/ Hints for Success

PEOPLE

MISSION

INNOVATION



Common Mistakes



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- The reviewers did not find your central scientific question interesting.
- The preliminary data are weak, and call into question the feasibility of the proposal and the validity of your central hypothesis.
- The proverbial house of cards: the overall success of the grant is dependent on the outcome of a key experiment, which has yet to be performed.
- The scope of the project is too ambitious, with multiple hypotheses or rationales that pull the grant in disparate directions.
- The PI and or research team lacks the experience to carry out the proposed work.



Pitfalls and Planning



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- Know and anticipate your potential hurdles
 - Contracting actions
 - Regulatory review
 - Budgetary (Congress)
 - Agreements
 - Continuity
- Develop contingency plans
- Leverage available support and expertise



Hints for Success



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- Follow instructions exactly.
- State purpose and need up front.
- Read successful grants.
- Pay attention to review criteria.
- Assume an uninformed but intelligent reviewer.
- Submit, revise & resubmit.
- Build on previous successes, as these show promise of future success.



Hints for Success



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- Answer the “so what?” question
 - Why should this project be funded
 - What is the expected impact if successful?
- Have statement from a DoD decision maker or end user representative
 - States how results from the proposed work 1) will be applied to the mission 2) what the *potential* impact could be
 - Impact could include procurement or change in operations, clinical practice, processes, or procedures
- Include operationally relevant injects
 - Identify deficiency, capability gap, or requirement that proposal will address or will be enhanced
 - If possible, reference After Action Reports, Lessons Learned, or other operationally-related reports



Hints for Success



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- Provide details how technology/change to a clinical practice will lead to better outcomes, not just better test!
- Avoid using weak, passive words like “can”, “may”, “could/should”, etc.
 - Use direct words (i.e. “will” if successful)
- Focus proposal(s) on unique mission aspects or areas
 - Avoid broad-based statements for general purpose use
 - Should be sharp and defined for specific issues & opportunities
 - Address mission deficiencies and/or operational enhancement
 - **NEED A STRONG IMPACT STATEMENT!**
- Collaborate whenever possible (proposals that involve two or more services are usually rated higher)
- Discuss ideas and pre-review (if possible) with JPC, end-users, and other services to gain advocacy and insight



59 MDW/ST Contact Information



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59 MDW
Science & Technology
210-292-2097

Usaf.jbsa.59-mdw.mbx.59-mdw-st@mail.mil

Victor L. Sylvia, Ph.D.
Senior Research Scientist/Ctr
Office of the Chief Scientist
1632 Nellis ST, Bldg B5406, Rm B215
JBSA-Lackland, TX
victor.l.sylvia2.ctr@mail.mil
Office: 210-292-3513

Science & Technology



**Readiness, Healthcare,
Education, Training, and
Research**

Vision: Grow Medical Leaders, Drive Innovations in Patient Care and Readiness

Mission: Conduct clinical studies and translational research and apply knowledge gained to enhance performance, protect the force, and advance medical care and capabilities across the global health system



**Chief Scientist
Science and Technology
Providing operational
capability through...**



**Lead & Support
Research**

**Advance Modernization
Efforts**

**Foster and Build
Collaborations**

**Address End User
Needs**

**Ensure Scientific
Excellence and
Programmatic Relevance**

**Wing, SAUSHEC,
AFMS, LAF, ASD/OSD,
Joint Cmts / S&T, Adv
Dev liaisons**



Research Funding at Science & Technology



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What help and support does S & T provide to grant seekers?

ST scientists can help you in different ways to develop your proposals:

- Ideas, concepts; match with missions, priorities, and gaps
- Reviews, feedback, and suggestions to improve proposals
- Help with guidance in writing manuscripts

Recommendations for New Researchers

- Stay abreast of new ideas and technologies
- Familiarize yourself with focus gaps
- Network with internal and external collaborators

External Collaboration & Agreements

The 59MDW/ST has an **ORTA** office!

Office of Research and Technology Applications

Usaf.jbsa.59-mdw.mbx.59-mdw-st-technology-transfer-office@mail.mil



A Path to Funding at Science & Technology



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White Paper or Pre-Proposal

← 2-3 pages; depends on call;
needs overall budget estimate

↓
Review

← Denial

← Invitation to Write Full Proposal

↓
Full Proposal

↓
Review

← Denial

← Receive
Questions/Comments from
Reviewers

↓
Improved Full Proposal

↓
Acceptance of Proposal Letter!

↓
Congrats

← Denial

← Request Comments
from Reviewers

↓
Funded Proposal

PEOPLE

MISSION

INNOVATION



Discussion



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- Q&A
- “Grant Stories”

Questions?

