Research Committee
Funding Workshop:
Congressionally Directed Medical Research Program (CDMRP)

December 16, 2016
Overview

- DOD Structure
- How to find solicitations
- Pre-proposal
- Proposal submission
- Proposal review
- Post-award administration
What do they fund?

High-impact, innovative medical research directed by congress to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

- Clinical
- Experimental
- Some computational (not alone)
- VERY interested in products at the moment

Does not have to be immediately translational, but the closer it is to helping veterans or military the better.
How to find solicitations

http://cdmrp.army.mil/funding/

General BAA announcements also exist – DO NOT APPLY TO THOSE
# How to find solicitations

How to find solicitations for defense medical research and development program.

## FY16-17 Defense Medical Research and Development Program (DMRDP)

### FY17 Translational Simulation Research (TRANSfER) Award

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Program Announcement/Instructions</th>
<th>Release Date</th>
<th>Funding Amount</th>
<th>Submission Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY17 Translational Simulation Research (TRANSfER) Award</td>
<td>Extramural: Program Announcement</td>
<td>August 10, 2016</td>
<td>Maximum funding of $1,800,000 for direct costs (plus indirect costs)</td>
<td>Pre-Application (Preproposals): October 13, 2016</td>
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<tr>
<td></td>
<td>Application Instructions (external link)</td>
<td></td>
<td>Maximum period of performance is 2 Years</td>
<td>Extramural Application: February 2, 2017</td>
</tr>
<tr>
<td></td>
<td>Intramural: Program Announcement</td>
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<td>Extramural Application: February 8, 2017</td>
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<tr>
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<td>Application Instructions (external link)</td>
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<td>Intramural Application: February 8, 2017</td>
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### FY17 Developing Models for Military Medical Training from Field Data Collected from Sensors (MATADOR) Award

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<tr>
<td>FY17 Developing Models for Military Medical Training from Field Data Collected from Sensors (MATADOR) Award</td>
<td>Extramural: Program Announcement</td>
<td>September 19, 2016</td>
<td>Maximum funding of $750,000 in total costs (direct plus indirect costs)</td>
<td>Pre-Application: November 14, 2016</td>
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<tr>
<td></td>
<td>Application Instructions (external link)</td>
<td></td>
<td>Period of performance should not exceed 2 Years</td>
<td>Extramural Application: March 1, 2017</td>
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<tr>
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<td>Intramural: Program Announcement</td>
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<td>Extramural Application: March 1, 2017</td>
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### FY17 Hearing and Balance Research Award

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<th>FY17 Hearing and Balance Research Award</th>
<th>Extramural: Program Announcement</th>
<th>November 1, 2016</th>
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<td>Application Instructions (external link)</td>
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### FY17 Utilizing Machine Learning and Artificial Intelligence for Medical Training Needs (MACH Learning) Award

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Easiest Way to Browse
General Tips Before you Start

• Don’t reach out to the program managers
  – Pre-proposal stage eliminates the ‘is this appropriate’ question

• If you have access to someone in the military (military hospitals, research centers, etc), ask them what the most pressing problems are

• Need clinical collaborators – even if as consultants

• Program announcements are descriptive and complete. Follow them to the letter.
Application Process – Pre-proposal

• Pre-application
  – Abstract (4000 characters)
  – Specific Hypothesis/Aims (1500 characters)
  – Scientific Rationale (1500 characters)
  – Approach/Methods (4000 characters)
  – Research Timeline (1500 characters)
  – Total estimated budget (4000 characters/prefab categories)
  – Biosketch for PI (8000 characters)
  – Applicant and Key Personnel (4000 characters)
  – List of relevant publications (4000 characters)
  – Current/Pending support (4000 characters)
Full Proposal – Typical Docs

• Project Narrative (10 pages)
  – Intro & background (5.5 pages)
  – Objectives & specific aims
  – Research strategy
• Statement of Work (2 pages)
• Technical Abstract
• Lay Abstract
• Impact and Military Benefit (1 page)
• Quad chart (1 powerpoint slide)
• Supporting Documents (21 pages)
• +biosketches, letters of support
## Review Process

<table>
<thead>
<tr>
<th></th>
<th>Document Description</th>
<th>Responsible Party</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Project Narrative (15-page)</td>
<td>Biostatistician</td>
</tr>
<tr>
<td>2</td>
<td>Supporting Documentation</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Technical Abstract (1-page)</td>
<td>Technology Transfer Specialist, Biostatistician</td>
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<tr>
<td>4</td>
<td>Lay Abstract (1-page)</td>
<td>Consumer</td>
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<tr>
<td>5</td>
<td>Statement of Work (3-page)</td>
<td></td>
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<tr>
<td>6</td>
<td>Military Benefit and Impact (1-page)</td>
<td>Consumer</td>
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<tr>
<td>7</td>
<td>Transition Plan (2-page)</td>
<td>Technology Transfer Specialist</td>
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<tr>
<td>8</td>
<td>Current Quad Chart (1-page)</td>
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<tr>
<td>9</td>
<td>PI Eligibility Statement (1-page) (if applicable; required for FL 1/NI)</td>
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<tr>
<td>10</td>
<td>IND/IDE Documentation (if applicable)</td>
<td>Technology Transfer Specialist</td>
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<tr>
<td>11</td>
<td>Human Subject Recruitment and Safety Procedures (if applicable, required for studies recruiting human subjects)</td>
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</tr>
<tr>
<td>12</td>
<td>Data Management (if applicable, required for studies recruiting human subjects)</td>
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<tr>
<td></td>
<td>- Senior/Key Person Profile</td>
<td></td>
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<tr>
<td></td>
<td>- Budget</td>
<td></td>
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<tr>
<td>13</td>
<td>Collaborating DoD Military Facility Budget Form (if applicable)</td>
<td></td>
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### Review Process

<table>
<thead>
<tr>
<th>Scored</th>
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</table>
| • Research Strategy and Feasibility *(Biostatistician)*  
• Military Benefit and Impact *(Consumer)*  
• Personnel  
• Transition Plan *(Technology Transfer Specialist)* | **Equal Importance** |

<table>
<thead>
<tr>
<th>Unscored</th>
<th></th>
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</table>
| • Environment  
• Budget  
• Application Presentation |  |
Research Strategy and Feasibility

- How well the preliminary data and scientific rationale support the research project.
- How relevant and applicable the proposed research and findings are to at least one of the FY16 OPORP OORA/PORA Focus Areas, and areas of encouragement, if applicable.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How consistent the methods and procedures are with sound research design.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- Whether the research can be completed within the proposed period of performance.
- To what degree the statistical model and data analysis plan are suitable for the planned study.
- How well the PI has outlined a plan for management and sharing of research data as appropriate for the type of study.
Research Strategy and Feasibility (con’t)

• For clinical trials and research involving human subjects:
  – How well the PI describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
  – How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and the process for obtaining informed consent.
  – If applicable, whether there is evidence demonstrating availability of the device/intervention from its source for the duration of the proposed study.
Military Benefit and Impact

- How well the PI describes the potential immediate and long-term effect on patient care.
- The potential immediate or long-term benefit and usability of the proposed research on the health and well-being of Service members, Veterans, and/or their families or communities.
Personnel

- How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research or clinical trial.
- How the PI’s record of accomplishment demonstrates his/her potential for contributing to the orthotics or prosthetics research field and completing the proposed work.
- Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate.
- How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
Transition Plan

- Whether the funding strategy described to bring the anticipated research outcome(s) to the next level of development and/or delivery to the military or civilian market is appropriate.
- Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
- How the schedule and milestones for bringing the outcome(s) to the next level of development are appropriate.
- How well the risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- How well the application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.
Review Process

Unscored Criteria

• **Environment**
  - To what degree the scientific environment and the accessibility of institutional/organizational resources support the proposed research.
  - Whether the quality and extent of institutional support are appropriate for the proposed project.

• **Budget**
  - Whether the budget is appropriate for the proposed research and is within the limits of this Program Announcement/Funding Opportunity.

• **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.
Post-Award Administration

• Reports
  – Quarterly reports - pain, but having grad student do initial draft helps. They do read them!!
  – Annual reports – not a pain because you just need to compile you quarterly reports.

• Funding flexibility
  – For me.. very. Not sure that’s true with all programs

• Human and animals studies
  – must get IRB and IACUC approval through them as well as UofU. Will take a long time.
  – VA medical system is a nightmare to navigate