Suggested Strategies for Assembling a Generic Statement of Work

NOTE: This document is meant to provide recommendations for the preparation of a generic Statement of Work (SOW) associated with a research study. **Please refer to the Funding Opportunity Announcement and General Application Instructions for any specific SOW requirements.**

The SOW is used by the Congressionally Directed Medical Research Programs (CDMRP) to assess progress in completion of the scope of the work outlined in the proposal. It serves as the synopsis of the entire project. During the entire period of performance, CDMRP will refer to this document to assess scientific progress and success. The SOW should provide sufficient detail that upon reading, an individual unfamiliar with the project can have a general understanding of the intent and approaches without referring to the proposal. However, directly copying narrative from the proposal is not recommended.

Please consider the points below and include the following information (where applicable) when drafting your SOW:

1. Date your SOW according to when it was written/submitted/last edited.
2. List all study sites that are receiving Department of Defense (DOD) funds for the proposed project to include: partnering Principal Investigators (PIs), sub-awardees or any other site where DOD-funded work is being performed.
3. Provide the specific aims as listed in the proposal.
4. Under each Specific Aim list associated tasks and subtasks. Please use 1-2 concise statements to describe all key experiments from the proposal in the SOW. Detailed methodology is not necessary; state the goal of the task/subtask and then provide general types of experiment(s) that will be used to achieve that goal. (Example: Assess RNA expression of XYZ).
5. Next to each task/subtask indicate the study site that is responsible for completion by placing an "X" in the appropriate column.
6. Provide a cohesive timeline that covers the entire period of performance and indicates the months during which each task is expected to be performed. For example, Major Task 1 to occur in Months 1-3, Major Task 2 to occur in Months 2-6.
7. If performing research involving animals, include a subtask for local institutional animal care and use committee (IACUC) and United States Army Medical Research & Development Command (USAMRDC) Animal Care and Use Review Office (ACURO) approval. Make sure to update the timeline of any tasks involving animal research so that they do not overlap with the time period designated for ACURO review/approval.
   NOTE: ACURO approval must in be place before using DOD funds for the proposed animal work.
   Please see: https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro for more details.
8. If performing research involving humans, human anatomical substances, cadavers, or human cells (excluding commercially available cell lines) include a subtask for local institutional review board (IRB) and USAMRDC Office of Human Research Oversight (OHRO). Make sure to update the timeline of any tasks involving these resources so that they do not overlap with the time period designated for OHRO review/approval.
   NOTE: OHRO approval must be in place before using DOD funds to conduct any research involving human subjects/material as outlined in OHRO's guidance.
   Please see: https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for more details.
9. For all tasks/subtasks involving animals or human subjects/human anatomical substances/human cells (including cell lines), please indicate the species/strain, source, and numbers required as appropriate. A table containing this information can also be included at the end of the SOW.

10. If conducting a collaborative study with the Military Health System (MHS), a Military Treatment Facility (MTF), or if your research involves access to active duty military patient populations and/or DOD resources and databases consider additional agreements that need to be established before the study can be conducted. Include subtasks associated with the establishments of Cooperative Research and Development Agreements (CRADAs), Memoranda of Understanding (MOU), Memoranda of Agreement (MOA), Data Sharing Agreements (DSAs), Material Transfer Agreements (MTAs) or Clinical Trial Agreements (CTAs).
11. Please include all regulatory milestones/endpoints in the SOW, if applicable. Examples: U.S. Food and Drug Administration (FDA) communication, Investigative New Drug/Investigational Device Exemption (IND/IDE) pre-submission, IND/IDE submission, IND/IDE clearance etc.
12. Define all abbreviations upon first use or include an abbreviation list at the end of the SOW.

The below fictitious SOW is completed and is meant to serve as an example of how to structure a generic research SOW. All tasks/subtasks and milestones should be modified and adjusted as appropriate to align with the proposal. A blank SOW template is available for download on eBRAP (https://ebrap.org/eBRAP/public/Program.htm**).**

STATEMENT OF WORK – Month/Day/Year
PROPOSED START DATE Month/Day/Year

Site 1: Generic State University [GSU]
Address line 1
Address line 2
PI: John Smith, PhD

Site 2: *Only add information for an additional site if that site is receiving funds to conduct research outlined in the SOW*
**Delete "Site 2" header and column if not used.*

Specific Aim 1: To characterize ncRNA-999	**Timeline (Months)**	**Site 1 GSU**	***Site 2****
Major Task 1: Characterize ncRNA-999 in cell lines			
For each subtask, concisely describe the goal of the subtask and the general type of experiment(s) that will be used to achieve that goal. Include the following as appropriate: • Indicate the cell line(s) to be used, species, and source, as appropriate. • For subtasks involving animals, indicate the specific strain/model to be used and the number required. • For subtasks involving human use (human subjects, human anatomical substances, or human-derived primary cells or cell lines) please include subject/sample numbers and source(s) as appropriate. • It is often helpful to include the experimental groups and/or include your control populations. If animal and/or human studies are proposed, be sure to include IACUC/ACURO and/or IRB/OHRO regulatory approval subtasks, respectively, prior to the research specific tasks.			
Subtask 1: Examine ncRNA-999 expression levels in cancer cells using PCR Cell lines used: AAX-92, XGEN123 [Cell line company/source]	1-6	X	
Subtask 2: Identify ncRNA-999 targets in cancer cells using DNA microarrays [Microarrays-R-US] Cell lines used: AAX-92, XGEN123 [Cell line company/source]	7-12	X	
Subtask 3: Characterize ncRNA-999 as a tumor suppressor by overexpressing ncRNA-999 and measuring tumor growth Cell lines used: AAX-92, XGEN123 [Cell line company/source]	12-14	X	

Milestone(s) Achieved: identification of specific gene targets of ncRNA-999 in various cancer cell lines	14		
Specific Aim 2: Determine the role of ncRNA-999 in tumor formation in nude mice			
Major Task 2: Development of ncRNA-999-expressing plasmids			
Subtask 1: Develop lentiviral plasmids containing inducible ncRNA-999 under control of inducible Tet-a promoter	14-15	X	
Subtask 2: Generate stable cell lines expressing plasmids developed in task 3.1 Cell lines used: AAX-92 [Cell line company/source]	15-16	X	
Milestone(s) Achieved: Production of stable cell lines capable of inducing ncRNA-999	16		
Major Task 3: Mouse studies with ncRNA-999 cell lines			
Subtask 1: Submit documents for ACURO approvals	13-17	X	
Milestone(s) Achieved: Obtain ACURO approval	17		
Subtask 2: Implantation of stable cell lines produced in task 3.2 and monitoring of survival in mice (BALB/c, Charles River) [12 mice per group x 2 groups = 24 mice total]	16-21	X	
Subtask 3: Biochemical characterization of tumors to analyze ncRNA-999 targets identified in task 2.2	21-24	X	
Milestone(s) Achieved: Characterization of effects of ncRNA-999 on tumor growth in vivo; publication of 1-2 peer reviewed papers	24		

If human subjects are involved in the proposed study, please provide the projected quarterly enrollment in the following table. Please remove if funds from this project are not being used to support human subjects research.

Projected Quarterly Enrollment

	Year 1				Year 2			
Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Site 1	14	14	42	42	42	42	28	8
Target Enrollment (cumulative)	**14**	**28**	**70**	**112**	**154**	**196**	**224**	**232**

Abbreviations List (if necessary)

Note: The Government reserves the right to request a revised SOW format and/or additional information.