Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work

NOTE: This document is meant to provide recommendations for the preparation of a Statement of Work (SOW) associated with a Clinical Trial/Clinical Research study. Please refer to the Funding Opportunity Announcement (FOA) and General Application Instructions for any specific SOW requirements, **including key regulatory milestones**.

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, including addresses with country where the work will be performed, 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. If conducting a multisite cooperative clinical study within the United States identify the site that will be the central single Institutional Review Board (IRB) of record.
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 and key personnel that is responsible for completion by listing the initials of the key personnel 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 conducting a study utilizing a drug or device for an indication not currently approved by the U.S. Food and Drug Administration (FDA) include subtasks and milestones associated with Investigational New Drug (IND) or Investigational Device Exemption (IDE) submission and notification to proceed.
8. If your study includes the clinical evaluation of an investigational product at international sites, include subtasks and milestones related to the application for approval to proceed from the relevant national regulatory agency of the host country(ies).
9. 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 Department of Defense (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).

10. Clinical trials/clinical research studies are subject to United States Army Medical Research & Development Command (USAMRDC) Office of Human Research Oversight (OHRO) review following IRB approval. Includes tasks/subtasks associated with obtaining the initial IRB approval and secondary OHRO review for each study that is to be conducted.
    - If conducting a multisite cooperative clinical study, include subtasks for review and approval of the master protocol and consent form by the central IRB of record. Include milestones for implementation and approval of satellite study locations. Subtasks associated with review and approval by the USAMRDC OHRO should follow IRB 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.
11. The quarterly projected subject enrollment goals should be summarized on a participating site basis in a table at the end of the SOW. If proposing multiple clinical studies separate tables should be prepared for each study.
12. If conducting a clinical trial, include a subtask for study registration with the National Institutes of Health (NIH) clinical trial registry www.clinicaltrials.gov.
13. If applicable, include required study initiation milestones as outlined in the FOA.
14. If performing research involving animals, include a subtask for local Institutional Animal Care and Use Committee (IACUC) and 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.
15. If performing research involving human anatomical substances, cadavers, or human cells (excluding commercially available cell lines) include a subtask for local IRB and USAMRDC 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 in be place before using DOD funds for the proposed studies. Please see: https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for more details.
16. For all tasks/subtasks involving animals or human anatomical substances/human cells (including cell lines), please indicate the species/strain, source, sex and numbers required as appropriate. A table containing this information can also be included at the end of the SOW.
17. 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 clinical 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: State University (State Univ.)
100 Circle Circle
Town, TX 10000
United States
PI: John Coltrane, PhD (JC)
Coordinator: Billy Holiday, PhD (BH)
Data Core Manager: Charlie Parker, PhD (CP)
Central IRB

Site 2: Air Force Hall Medical Center
100 Drive Drive
City, CO 30000
United States
PI: Dave Brubeck, PhD (DB)
Coordinator: Dizzy Gillespie, PhD (DG)

Site 3: Army Medical Center
200 Street Street
Town, GA 40000
United States
PI: Miles Davis, PhD (MD)

Site 4: Veteran's Administration Medical Center
300 Way Way
City, NY 50000
United States
PI: Duke Ellington, PhD (DE)

Study 1 Specific Aims 1&2: (1)To determine the adaptations of the standard Jazz protocol that are needed to implement an outdoor-based treatment in outdoor care; (2) To develop a model of care for musical exposure therapy treatment of PTSD in outdoor care settings including treatment length.	**Timeline**	**Research Sites**			
	Months	**State Univ.**	**AFHMC**	**AMC**	**VA**
Major Task 1: Adapt Standard Jazz Protocol for Outdoor Care Setting					
Subtask 1: Prepare Regulatory Documents and Research Protocol for Study 1					
If Applicable, coordinate with Sites for CRADA, MOU, MOA, and/or DSA submission	1-3	JC/BH	DG	MD	DE
If Applicable, coordinate with Sites for MTAs or CTAs submission	1-3	JC/BH	DG	MD	DE
If Applicable, coordinate with Sites for NDAs.	1-3	JC/BH	DG	MD	DE
If applicable, indicate time required for submission and exemption of an IND application or an IDE application to the FDA	1-3	JC/BH	DG	MD	DE

Refine eligibility criteria, exclusion criteria, screening protocol	1-3	JC/BH	DB	MD	DE
Finalize consent form & human subjects protocol	1-3	JC/BH	DB	MD	DE
Coordinate with Sites for IRB protocol submission	1-3	JC/BH	DG	MD	DE
Coordinate with Sites for State University IRB review	1-6	JC/BH			
Coordinate with Sites for USAMRDC review (OHARO/OHRO)	1-6	JC/BH	DG	MD	DE
Clinicaltrial.gov registration	6	JC/BH			
Submit amendments, adverse events and protocol deviations as needed	As Needed	JC/BH	DG	MD	DE
Coordinate with Sites for annual IRB report for continuing review	Annually	JC/BH	DG	MD	DE
Milestone Achieved: Local IRB approval at AFHMC, AMC #1, and VA#1	3	JC/BH	DG	MD	DE
Milestone Achieved: OHRO approval for all protocols and local IRB approval through State Univ.	6	JC/BH	DG	MD	DE
Major Task 2: Coordinate Study Staff for Clinical Trials					
Subtask1: Hiring and Training of Study Staff					
Coordinate with Sites for job descriptions design	1-4	JC/BH	DG	MD	DE
Advertise and interview for project related staff	4-8	JC/BH	DG	MD	DE
Coordinate for space allocation for new staff	1-7		DG	MD	DE
Coordinate with Sites for Independent Evaluators hiring and trainings	5-11	JC/BH	DG	MD	DE
Coordinate with Sites for training Independent Evaluators until 100% concordance	8-11	JC/BH	DG	MD	DE
Milestone Achieved: Research staff trained	8-11	JC/BH	DG	MD	DE
Subtask 2: Facilitate and Coordinate with Sites for hiring, training, supervision and fidelity checks as needed for attrition	8-20	JC/BH	DG	MD	DE
Coordinate with Sites for training Independent Evaluators to maintain 100% concordance	8-20	JC/BH	DG	MD	DE
Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of both clinical trials	8-20	JC/BH	DG	MD	DE
Study 1 Specific Aims 3, 4 & 5: (3) To develop a manualized outdoor care treatment protocol for combat-related PTSD; (4) To determine the level of PTSD symptom severity that is most suitable for long outdoor-based jazz treatments in outdoor care; and (5) To conduct a small (N = 35) clinical replication series study of the effectiveness of					

Jazz therapy for the treatment of PTSD symptoms in outdoor care settings.					
Major Task 3: Prepare Research Protocol for Study 2					
Subtask 1: Refine research protocol for study 2 based on findings of study 1	20-25	JC/BH	DG	MD	DE
Milestone Achieved: protocol for study 2 developed	25-30	JC/BH	DG	MD	DE
Major Task 4: Participant Recruitment, Therapy, Participant Evaluation					
Subtask 1: Study 1, Pilot Study					
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-8	JC/BH/CP	DG	MD	DE
Finalize assessment measurements	1-4	JC/BH/CP	DG	MD	DE
Milestone Achieved: 1st participant consented, screened and enrolled	7-30		DG	MD	DE
Milestone Achieved: Study 1 begins	7-30		DG	MD	DE
Begin subject recruitment	7-30		DG	MD	DE
Participants complete assigned treatment regimen over 12 weeks - 4 session outdoor care PTSD protocol N=35	7-30		DG N=17	MD N=7	DE N=11
Complete follow-up assessments 3 months after completion of the Outdoor Jazz treatment.	10-33		DB	MD	DE
Milestone Achieved: Report findings from 3 month follow-up assessments	34-36		DG	MD	DE
Subtask 2: Determine modifications of Outdoor protocol that are needed to implement Outdoor-based Jazz treatment in outdoor care	1-4	JC/BH	DB	MD	DE
Develop a model of care for outdoor therapy treatment of PTSD in outdoor care	1-4	JC/BH/CP	DB	MD	DE
Develop a manualized outdoor care treatment protocol for combat-related PTSD	1-4	JC/BH/CP	DB	MD	DE
Milestone Achieved: Treatment protocol finalized	5-7	JC/BH/CP	DG	MD	DE
Study 2 Specific Aim: To conduct a small randomized clinical trial (N = 60) to evaluate the efficacy of Outdoor Jazz therapy for OIF/OEF veterans in outdoor care as compared to treatment as usual.					
Major Task 5: Randomized Controlled Trial, Study 2					
Subtask 1: Conduct Study, Report Findings					
Analyze, measure and determine the appropriate level of PTSD symptom severity that is most suitable for outdoor-based treatments in outdoor care	31-36		DG	MD	DE

Milestone Achieved: 1st participant consented, screened and enrolled in study 2	37-50		DG	MD	
Milestone Achieved: Study 2 begins	37-50		DG	MD	
Study 2 - Screen potential participants at outdoor care providers using outdoor care PTSD process in Study 1 and consent (N=60)	37-50		DG N=30	MD N=30	DE N=0
Study 2 - evaluate and assign participants to one of the two randomized groups	37-50		DG	MD	
Study 2 - assess all participants at the 3, 6, and 12 month timeframe	37-50		DB	MD	
Study 2 - evaluate and measure the efficacy of Outdoor Jazz therapy-PTSD for OIF/OEF veterans in outdoor care	37-50		DB	MD	
Milestone Achieved: Report findings from overall studies	51-59	JC/BH/CP	DG	MD	DE
Major Task 6: Data Analysis					
Subtask 1: Coordinate with Sites & Data Core for monitoring data collection rates and data quality	51-59	CP	DG	MD	DE
Perform all analyses according to specifications, share output and finding with all investigators	51-59	CP	DG	MD	DE
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD)	51-59	CP	DG	MD	DE
Milestone Achieved: Report results from data analyses	51-59	JC	DG	MD	DE

Projected Quarterly Enrollment

	Year 1				Year 2				Year 3		Total
Target Enrollment Pilot Study (#1) (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	
AFHMC	-	-	5	5	4	1	2	0	0	0	17
AMC #1	-	-	0	2	1	3	0	1	0	0	7
VA #1	-	-	0	0	0	1	2	4	3	1	11
Target Enrollment (cumulative)	**-**	**-**	**5**	**7**	**5**	**5**	**4**	**5**	**3**	**1**	**35**

	Year 3				Year 4				Total
Target Enrollment Randomized Control Study (#2) (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
AFHMC	3	3	6	6	6	6	0	0	30
AMC #1	3	3	6	6	6	6	0	0	30
VA #1	0	0	0	0	0	0	0	0	0
Target Enrollment (cumulative)	**6**	**6**	**12**	**12**	**12**	**12**	**0**	**0**	**60**

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

Abbreviations List (if necessary)