

DEPARTMENT OF THE NAVY NAVAL SEA SYSTEMS COMMAND 1333 ISAAC HULL AVE SE WASHINGTON NAVY YARD DC 20376-0001

IN REPLY REFER TO

NAVSEAINST 3900.10A Ser 00C-0051/503 6 Nov 2018

NAVSEA INSTRUCTION 3900.10A

From: Commander, Naval Sea Systems Command

Subj: MANAGEMENT OF THE DEEP SUBMERGENCE BIOMEDICAL DEVELOPMENT PROGRAM

Ref: (a) NAPDD #587-873, Deep Submergence Biomedical Development, 23 Nov 1999

(b) CNO ltr 10560 Ser N873/7U657908 of 30 Jan 97

(c) NAVSEA ltr 10560 Ser 00C/0017 of 24 Mar 97

(d) OUSD (ATL) memo "DoD Source Selection Procedures" of 4 Mar 11

Encl: (1) DSBD Incremental Report Template

(2) DSBD Completion Report Template

(3) DSBD Fleet Executive Summary Template

- 1. <u>Purpose</u>. This instruction implements policy for the management of the Deep Submergence Biomedical Development (DSBD) Program, Project 0099, PE 0603713N, per references (a) and (b). This is a major revision to the previous instruction and should be read in its entirety.
- a. Only sample formats for required reports have been retained as enclosures within the instruction.
- b. Previously enclosed sample formats for pre-proposals and full proposals are now provided in conjunction with the posting of each subsequent Broad Agency Announcement (BAA) on the Federal Business Opportunities Web site, and the remaining enclosures were determined to be internal program office documents.
- 2. Cancellation. NAVSEAINST 3900.10.
- 3. <u>Background</u>. In 1997, responding to direction provided in reference (b), Naval Sea Systems Command (NAVSEA) assumed responsibility for managing the DSBD program and providing the program manager. The authority for managing the program was vested with the Supervisor of Salvage and Diving (SEA 00C), per reference (c). A senior Undersea Medical Officer (UMO) billet was permanently established in the office of SEA 00C to ensure successful program planning and execution. The primary objective of the DSBD program is to sponsor undersea biomedical research to improve diver health, safety and performance in all operational settings and to enhance the survivability of submariners in a disabled submarine (DISSUB) incident. The specific high-level objectives are outlined in reference (a), with detailed research areas of interest provided in the program's periodically updated and released BAA.

4. Responsibilities

- a. Supervisor of Salvage and Diving:
 - (1) Retains overall responsibility for the management of DSBD.
- (2) Ensures clear lines of communication are maintained with the DSBD Program Resource Sponsor, Office of the Chief of Naval Operations, Undersea Warfare Division, N97 (OPNAV N97).
- (3) Ensures the program manager meets the requirements contained and referenced in this instruction.
 - b. DSBD Program Manager (PM):
- (1) Reports to SEA 00C, is assigned the internal office code of SEA 00CM, and is accountable to SEA 00C for program management.
- (2) Will be an O-6 (or senior O-5) Undersea Medical Officer with significant experience in Undersea Biomedical Research and Development (R&D) as well as a background in operational medicine. Each candidate for the DSBD PM position will be nominated by the Navy Medicine UMO Specialty Leader with concurrence required from SEA 00C.
 - (3) Will perform the following functions:
- (a) Define operational requirements with a focus on capability gaps in collaboration with OPNAV N97, SEA 00C, the Director of Diving Programs (SEA 00C3), and the Supervisor of Diving (SEA 00C3B).
- (b) Develop short and long range Undersea Biomedical R&D plans through regular communications with Undersea Medicine and Undersea Warfare communities.
 - (c) Establish and convene the Technical Advisory Board (TAB).
- (d) Draft appropriate BAAs for public release, at least biennially, to disseminate a broad call for pre-proposals and full proposals from a wide range of organizations and experts based on operational priorities and capability gaps.
 - (e) Set the pre-proposal and proposal evaluation criteria.
 - (f) Formalize, document, and archive the evaluation process.

- (g) Using input from the TAB, select proposals for sponsorship/funding, with SEA 00C and OPNAV N97 concurrence.
 - (h) Issue program guidance.
 - (i) Establish contracting mechanisms for non-governmental performers.
 - (j) Distribute funding based on program priorities.
 - (k) Foster innovative Undersea Biomedical R&D.
- (l) Provide budget, progress, and justification input to higher authority as needed or requested.
 - (m) Ensure funded projects are completed on time.
 - (n) Facilitate product and guidance transitions to the fleet.
 - (o) Publicize the results of significant Undersea Biomedical R&D advances.
 - (p) Create archival documentation and retrieval processes.
- (q) Support and encourage sustained subject matter expertise at Navy laboratories and university partner research institutions.
 - (r) Provide medical R&D support for international information exchange programs.
- c. <u>Technical Advisory Board (TAB)</u>. The TAB supports the source selection process per reference (d) by reviewing proposals and providing input to the DSBD PM about the individual merit, relevance, and value of the submitted research projects. The TAB is comprised of four or more independent members representing operational, research, or scientific areas of experience and expertise. The DSBD PM convenes and supervises the deliberations of the TAB, recruiting its members from SEA 00C personnel, fleet subject matter experts, and UMOs representing undersea warfare specialty communities. All TAB members complete non-disclosure and noconflict-of-interest statements prior to participating in proposal review and scoring.

5. Action

- a. Research projects are selected for funding as follows:
- (1) The DSBD PM will issue a call for pre-proposals as a function of current and anticipated Navy requirements. Pre-proposals, and further documentation as needed, are submitted in the standard format of the pre-proposal template provided in the BAA. The

deadline for receipt of pre-proposals is stated in the BAA. The DSBD PM will acknowledge receipt and notify the contracting officer regarding preproposals received from non-governmental institutions.

- (2) The DSBD PM, in cooperation with the TAB, will screen the pre-proposals according to the procedures outlined in the approved source selection plan, and select those projects which show the most promise, have the highest priority, or otherwise are most likely to meet Navy requirements.
- (3) Successful pre-proposal submitters will be invited to submit full proposals, using the format found in the full proposal template provided in the BAA. The DSBD PM, in concert with the contracting officer when appropriate, will work with submitters to ensure that Navy needs will be the primary consideration for the research. The DSBD PM and the contracting officer will work together to develop methods for the DSBD PM to communicate with nongovernmental submitters when changes in the planned research are deemed desirable in order to meet Navy needs.
- (4) Once all full proposals are received, the DSBD PM will forward them to the members of the TAB. Each TAB member reviews and scores each proposal independently, following criteria specified in the approved Source Selection Plan.
- (5) The DSBD PM will sponsor TAB members to attend an annual in-person board meeting, with the schedule determined by the DSBD PM, subject to travel and financial restrictions.
- (6) The initial TAB proposal review and scoring results will be collected by the DSBD PM for use during the annual TAB board meeting. The TAB, as led by the DSBD PM, will use the annual meeting to promote in-depth discussion of each proposal, allowing each TAB member to advocate for or against each project based on operational priorities. TAB members will be permitted to modify their initial scores for each project based on the in-person discussions, and the DSBD PM will collect the final score sheets from each TAB member for each proposal prior to adjourning the meeting.
- (7) The DSBD PM, based on the cumulative scoring, resultant ranking, and the limits of available funding, with SEA 00C concurrence, will select the proposals to be funded. As resource sponsor, OPNAV N97 will be notified of the program selection results for review and concurrence.
- (8) The results of this selection process will be communicated to each submitter, successful or not, by the DSBD PM for the Department of Defense (DoD)/Government facilities, and by the contracting officer for contractors.
 - b. Research projects are funded as follows:

- (1) Funds for PE 0603713N are provided to the DSBD PM from the Navy, consistent with previously submitted budget documents. The DSBD PM issues, in writing, overall guidance regarding the allocation of funds to the various research projects, program initiatives and performing activities for the coming year. Once this guidance is approved by SEA 00C with concurrent notification provided to OPNAV N97, each principal investigator (PI) is notified.
- (2) Those performers (Government or contractor) selected for sponsorship by the DSBD program will be funded once the fiscal year funds have been released, as prioritized by the DSBD PM. The DSBD PM is responsible for initiating work orders to disseminate funds to Navy/other government laboratories and for submitting the required documentation to develop contracts with selected non-governmental research facilities in cooperation with the NAVSEA contracting officer.

c. Progress Reviews

- (1) The DSBD PM will maintain close communications with each sponsored PI throughout the respective project's period of performance, relying on telephone and email discussions as well as review of required semi-annual incremental reports. The DSBD PM will conduct site visits to individual laboratories or commands as needed to maintain oversight of sponsored work. The DSBD PM will also coordinate an annual program review, in collaboration with the Office of Naval Research Undersea Medicine Division when practical, where all performers are required to attend and present their ongoing work.
- (2) The DSBD PM will ensure key stakeholders are invited to attend the annual program review, including but not limited to OPNAV N97, SEA 00C, NAVSEA contracting officer/specialist, TAB members, PMS391, and representatives of joint program committee 5 (JPC-5), Navy Research Advanced Medical Development (AMD) Office, and the Defense Health Agency (DHA) J9.
- d. Reports. PIs will be responsible for providing incremental reports, completion reports, and fleet executive summaries to the DSBD PM using the schedules and formats in enclosures (1) through (3).

6. Records Management

a. Records created as a result of this instruction [notice, change transmittal], regardless of format or media, must be maintained and dispositioned for the standard subject identification codes (SSIC) 1000 through 13000 series per the records disposition schedules located on the Department of the Navy/Assistant for Administration (DON/AA), Directives and Records Management Division (DRMD) portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx.

- b. For questions concerning the management of records related to this instruction [notice, change transmittal] or the records disposition schedules, please contact your local records manager or the DON/AA DRMD program office.
- 7. Review and Effective Date. Per OPNAVINST 5215.17A, SEA 00C will review this instruction annually on the anniversary of its effective date to ensure applicability, currency, and consistency with Federal, DoD, SECNAV, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will automatically expire 5 years after effective date unless reissued or canceled prior to the 5-year anniversary date, or an extension has been granted.

Releasability and distribution:

This instruction is cleared for public release and is available electronically only via the NAVSEA Public Website located at http://www.navsea.navy.mil/Resources/Instructions/

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DSBD INCREMENTAL REPORT TEMPLATE

<u>Intent:</u> To describe project accomplishments and issues for the reporting period (defined below). This is not a cumulative report; information provided in previous incremental reports should not be repeated. All incremental reports will be collected, reviewed, acted-on as appropriate, and filed by the DSBD program manager (PM).

<u>Audience:</u> The incremental report should be written for the DSBD PM, to communicate interim progress and identify obstacles to successful completion of the project. These reports will not generally be shared beyond the program office, but rather, will provide the DSBD PM with an updated status of each project. This will permit informed discussion of each project with key stakeholders and resource sponsors. Circumstances that arise which may negatively impact completion of the project within the approved timeline and budget must be discussed with the DSBD program manager as soon as they are identified.

<u>Document Size:</u> 1-3 pages in length (attachments will not be considered as contributing to the document length).

<u>Document Type:</u> Microsoft Word (.docx) or portable document format (.pdf). PDF files must be text searchable.

<u>Due Date</u>: Every January 31 and July 31 for the duration of the project. If either date falls on a weekend, then reports should be submitted on the next regular workday. For new research projects, no report is required if the project funding was received less than 90 days prior to the due date. For research projects concluding within 90 days of a due date, the incremental report may be deferred in lieu of submission of the final completion report. If the final completion report will be delayed longer than 90 days from the incremental report due date, then an incremental report is required.

Sample Format (template below)
Naval Sea Systems Command
Deep Submergence Biomedical Development Program
Incremental Report
(Date)

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR (PI):

RESEARCH INSTITUTION:

TIME PERIOD COVERED BY REPORT: (e.g., 1 Aug 2018 - 31 Jan 2019)

PROJECT TIMELINE: (e.g., 1 Oct 2017 - 30 Sep 2020)

1. SUMMARY OF THE WORK PLAN – Abbreviated and concise.

2. MILESTONE STATUS: List each milestone and state whether progress is "on schedule", "ahead of schedule", or "delayed". If progress is delayed on a specific milestone, give the new start date (MM/YYYY), projected completion date, transition date, etc., and give the reason(s) for the milestone change. Provide updated table (below) as needed if timelines have been adjusted.

MILESTONE DESCRIPTION	1 st Yr				2 nd Yr				3 rd Yr			
	1	2	3	4	1	2	3	4	1	2	3	4
A. Subproject A. Short Title:												
1) Milestone A.1. description		S	С									
2) Milestone A.2. description			S	С								
3) Milestone A.3. description			S	С								
4) etc.				SC								
B. Subproject B. Short Title:												
1) Milestone B.1. description			S	\rightarrow	С							
2) Milestone B.2. description				D	S	С						
C. Subproject C. Short Title:												
1) Milestone C.1. description						S	\rightarrow	\rightarrow	R			

LEGEND: Planned Milestones: S = Start C = Complete R = Report D = Delayed

3. ACCOMPLISHMENTS:

- a. A concise statement (3 lines maximum) of the noteworthy progress accomplished under each milestone during the reporting period. This should not be a statement of cumulative progress, but should convey what happened in this aspect of the R&D effort during the reporting period.
- b. A short paragraph that puts the concise statement into context. (Why is the accomplishment significant?) Brief supporting data should be provided if results are unpublished; however, when possible, the reader should be referred to specific journal articles or technical reports for details. These supporting articles or reports may be included as attachments to the incremental report.
- c. Milestones under which no significant progress was made during the reporting period should be simply state "none". All active milestones should be addressed in the report.

- 4. ISSUES/PROBLEMS: Discuss anything the DSBD PM should know to assist, promote or protect the project. Any proposed revision of the original process, with rationales, should be provided. Approval or disapproval of suggested revisions will be decided and documented accordingly by the DSBD PM and communicated back to the PI. The DSBD PM will determine whether the issue requires discussion with higher authority.
- 5. FINANCIAL TRACKING: Provide current data on the status of expenditures and expenditure rates for each funded year of the project. Identify any issues preventing timely and consistent expenditure of funds.
- 6. WORK PRODUCTS: Provide citations for the following project deliverables, by category, if produced and available:
 - a. Journal publications
 - b. Technical Reports
 - c. Letter Reports to Fleet Users
 - d. Presentations and Abstracts
 - e. Patents
 - f. Cooperative Research and Development Agreements (CRADA)
 - g. Awards

Citations should be complete and should be written in the Vancouver style used by MEDLINE and PubMed. The style guide can be found at https://www.nlm.nih.gov/citingmedicine.

Example:

Fletcher MA, McKenna TM, Owens MH, Nadkarni VM. Effects of in vivo pentoxifylline on survival and ex vivo vascular contractility in a rat lipopolysaccharide shock model. Circ. Shock. 1992. 36:74-80.

If any product is pending (publication is listed as "in press", etc), the PI should provide the complete citation in the next incremental or completion report.

7. APPENDIX: Attach copies of journal publications, abstracts, and pre-prints. Also, provide any pictures, slides, transparencies, or samples that describe research accomplishments. These are invaluable aids for gaining or sustaining sponsor support.

DSBD COMPLETION REPORT TEMPLATE

<u>Intent:</u> To report the results and discuss the conclusions and recommendations derived from sponsored research, in the context of relevance for the Fleet and the warfighter. All Completion Reports will be collected, reviewed, acted-on, disseminated as appropriate, and archived by the DSBD Program Manager (PM).

<u>Audience</u>: The Completion Report should be written for a scientific audience (see format guidance below). All reports will be initially read and reviewed by the DSBD PM. Depending on the results and the content, the report will be considered for posting and distribution to Fleet stakeholders and peers within the undersea medicine biomedical research community. Completion Reports should be written to allow a "Distribution A: Approved for Public Release" marking to be applied whenever possible. If "Distribution A" labeling is impractical, the DSBD PM must be informed as soon as this limitation is identified.

<u>Document Size:</u> 20 page limit. Longer reports will be accepted if the additional length is necessary to provide a comprehensive work product. Attachments will not be considered as contributing to the document length.

<u>Document Type:</u> Microsoft Word (.docx) or Portable Document Format (.pdf). PDF files must be text searchable.

<u>Due Date:</u> No later than the final completion date of the project.

Sample Format (template below)
Naval Sea Systems Command
Deep Submergence Biomedical Development Program
Completion Report
(Date)

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR (PI):

RESEARCH INSTITUTION:

PROJECT TIMELINE: (e.g., 1 Oct 2017 - 30 Sep 2020)

- 1. ABSTRACT
- 2. INTRODUCTION Address specific aim/objectives of the project and the hypotheses being tested.

- 3. METHODS Self-explanatory
- 4. RESULTS Self-explanatory
- 5. DISCUSSION Focus on where the research findings impact the Fleet and warfighters. Speak to any pathways to transitioning the new knowledge to benefit the operational forces.
- 6. CONCLUSION Explore where the findings of the project should lead in terms of future research. Any anticipated technology transfer should be addressed here.
- 7. WORK PRODUCTS Provide citations for the following project deliverables, by category, if produced and available:
 - a. Journal publications
 - b. Technical Reports
 - c. Letter Reports to Fleet Users
 - d. Presentations and Abstracts
 - e. Patents
 - f. Cooperative Research and Development Agreements (CRADA)
 - g. Awards

Citations should be complete and should be written in the Vancouver style used by MEDLINE and PubMed. The style guide can be found at https://www.nlm.nih.gov/citingmedicine. For example:

Fletcher MA, McKenna TM, Owens MH, Nadkarni VM. Effects of in vivo pentoxifylline on survival and ex vivo vascular contractility in a rat lipopolysaccharide shock model. Circ. Shock. 1992. 36:74-80.

If any product is pending (publication is listed as "in press", etc), at the time of submission of the final Completion Report, the Principal Investigator must provide the DSBD Program Manager with a copy of the finished product when it becomes available, for inclusion in the DSBD Program files to allow final project closure.

8. TRANSITIONS - If the project results in follow-on research or development (DSBD sponsored or other), cite the program element and project receiving the transition, and the Start Year, End Year, and estimated first year funding.

9. REFERENCES – Self-explanatory

10. APPENDIX – Attach copies of journal publications, Technical Reports, abstracts, and/or preprints that have not been submitted in previous reports. Similarly, provide any pictures, slides, transparencies, or samples that describe research accomplishments. These are invaluable aids for gaining or sustaining sponsor support for future efforts.

3

DSBD FLEET EXECUTIVE SUMMARY TEMPLATE

<u>Intent:</u> Allow any reader with an operational and/or scientific interest in the subject, regardless of their technical knowledge, to understand the contents of the report and the relevance of the findings and recommendations.

<u>Audience:</u> The fleet executive summary (EXSUM) is meant for distribution to Navy medical and non-medical consumers of biomedical research results. It should be written to allow a "Distribution A: Approved for Public Release" marking to be applied to it.

<u>Document Size:</u> 1-3 pages in length.

<u>Document Type:</u> Microsoft Word (.docx) or portable document format (.pdf). PDF files must be text searchable.

<u>Due Date:</u> No later than the final completion date of the project.

Sample Format (template below)

Naval Sea Systems Command
Deep Submergence Biomedical Development Program
(EXSUM)
(Date)

TITLE OF PROJECT:

PRINCIPAL INVESTIGATOR (PI):

RESEARCH INSTITUTION:

PROJECT TIMELINE: (e.g., 1 Oct 2017 - 30 Sep 2020)

- 1. Project Summary: What is the research project and why was it conducted?
 - Provide a brief (2-3 sentences) description of the project.
 - What is the problem or issue?
 - What is the purpose of the research?
- 2. Conclusion or Summary of Findings: What were the major findings or results?
 - Provide a brief (2-3 sentences) description of the most significant findings.
 - What are the practical benefits of this research for the fleet?
 - Does the research provide enough information to influence policy decisions?

- 3. Background: What is the history of the research?
 - Did a specific event or issue provide the impetus for the research?
 - Is this a second or third phase to earlier research conducted by you or someone else?
 - Is this a "first-of-its-kind" research project?
- 4. Process (Methods): What process was used to conduct the research?
 - Provide a brief (2-3 sentences) description of the research process.
 - What was the length of the research number of months or years?
- 5. Recommendations: What future steps are needed in both the short-term and long-term?
 - Explain how the findings should inform actual policy or program changes.
 - What needs to be done before the research results can be implemented?
 - Is additional study needed?
 - Are there unresolved issues?
- 6. Other supporting information: This can include a listing of publications and/or technical reports produced as a result of the underlying research, which provide the scientific basis for the Fleet EXSUM. This will allow the reader to explore the topic in greater detail if desired by accessing the source document(s). (This is not a list of the references used to conduct the original research project.)
- 7. Contact Information: Provide the following:
 - Contact name
 - Phone number
 - Mailing address
 - E-mail address