DEPARTMENT OF THE NAVY

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

IN REPLY TO

NAVSEAINST 3900.10
Ser 00C/0006
4 FEB 2003

NAVSEA INSTRUCTION 3900.10

From: Commander, Naval Sea Systems Command (SEA 00C)

Subj: MANAGEMENT OF THE DEEP SUBMERGENCE BIOMEDICAL RESEARCH AND DEVELOPMENT PROGRAM

Ref: (a) NAPDD #587-873, Deep Submergence Biomedical Development, 23 Nov 99
(b) CNO ltr 10560 Ser N873/7U657908 of 30 Jan 97 CNO requirement
(c) NAVSEA ltr 10560 Ser 00C/0017 of 24 Mar 97

Encl: (1) Technical advisory board invitation letter (example)
(2) Pre-proposal format
(3) Proposal format
(4) Proposal evaluation form
(5) Incremental report format
(6) Completion report format

1. Purpose. Provide guidance for administering the Deep Submergence Biomedical Development Program, Project S0099, PE 0603713N.

2. Background. In 1997 responsibility for funding the Deep Submergence Biomedical Development Program was transferred from the Bureau of Medicine and Surgery (BUMED) to the Commander, Naval Sea Systems Command. The authority for managing the program was vested with the Supervisor of Salvage and Diving, (SEA-00C). In April 2001 a medical officer billet was placed in the office of SEA-00C for the purpose, among others, of assisting in the management of this program.

3. Action. All persons involved in the planning, execution or management of this program shall follow the procedures described in this letter

4. Program Objectives. This undersea biomedical R&D effort serves to enhance the U.S. Navy's capabilities in survival, escape and rescue from a disabled sunken submarine (DISSUB), and improve diver safety and performance in conventional settings. The specific objectives are outlined in references (a) and (b).

5. Program Management

a. Overall responsibility. As requested by the Chief of Naval Operations (CNO-N773), reference (c), the Director of Ocean Engineering (SEA 00C) accepts program management of the Deep Submergence Biomedical Development Project, reference (c).

b. Program Manager

(1) Location. The functional position is located within the offices of SEA 00C, is titled Program Manager, Deep Submergence Biomedical Development, and coded SEA 00CN.

(2) Qualifications. The Program Manager will be a senior (O-5 / O-6) Medical Department Officer with significant experience in Undersea Biomedical R&D. The Bureau of Medicine and Surgery (BUMED Codes M3F7 and M2) will nominate qualified individuals for this position, with concurrence by SEA 00C and CNO-N773.

(3) Responsibilities. The Program Manager will:

- Define operational requirements with the Supervisor of Diving (SEA 00C3B) and the Director of Diving Programs (SEA 00C3)
- Develop short and long range R&D plans
- Establish the Technical Advisory Board (TAB), (see Encl (1))
- Draft appropriate Broad Agency Announcements (BAA) for public release
- Set the evaluation criteria
- Issue call for pre-proposals
- Formalize and archive the evaluation process
- Select (with 00C3B and 00C3) the proposals approved for funding
- Issue program guidance
- Establish contracting mechanisms
- Distribute the funds
- Foster innovative R&D
- Provide budget, progress, and justification input to higher authority

- Ensure deliverables are on time
- Facilitate product transitions to the fleet
- Publicize the results of significant R&D advances
- Create archival documentation and retrieval processes
- Recruit new talent into the program
- Provide medical R&D support for international data exchange programs
- Request and receive assistance from subject matter experts as needed

(4) Accountability. The program manager reports to SEA 00C for day-to-day program management, and to CNO-N773 for resource matters.

c. Administrative Assistant. An administrative assistant (SEA 00CNA) will be responsible to the program manager for aiding in all aspects of this program.

6. The Funding Decision Process. Research projects are chosen and funded as follows:

a. The Program Manager issues a call for pre-proposals as a function of current and anticipated Navy requirements. Pre-proposals and further documentation are submitted in the format outlined in enclosure (2). The schedule for receipt of pre-proposals should be included in the BAA. The Program Manager will acknowledge receipt.

b. The Program Manager with the concurrence of the Supervisor of Diving and the Director of Diving Programs will screen the pre-proposals and select those which show the most promise, have the highest priority, or otherwise are most likely to meet Naval requirements.

c. Successful pre-proposal submitters are invited to submit full proposals, with the format outlined in enclosure (3). The Program Manager will work with submitters to ensure that Navy needs will be the primary consideration for the research.

d. The proposals are forwarded to the Deep Submergence Biomedical Development Technical Advisory Board (TAB), comprised of four or more independent members representing expertise in operational, research, and scientific areas. Each member rates each proposal independently in accordance with criteria specified in enclosure (4).

e. The TAB evaluations and recommendations are forwarded to the Program Manager for integration. The TAB then meets as a group with the Supervisor of Diving, the Director of Diving Programs, and the Program Manager, to discuss the results of their independent reviews, and make their final recommendations.

f. Proposals may be submitted at any time, without an initial pre-proposal. They will be considered as outlined below.

g. The Program Manager, with Supervisor of Diving and Director of Diving Programs concurrence, then decides efforts to be supported, at what level, with what priority, and with what degree of collaboration.

h. Feedback on the results of this process are provided to each submitter, successful or not, by the Program Manager.

i. The successful submitters receive contracts through Coastal Systems Station (CSS). Cooperation and interaction between the Program Manager, the submitter, and CSS will promote an efficient and successful contracting process.

7. Resource Flow

a. Funds for PE 0603713N are provided to the Program Manager from the Navy Comptroller in accordance with previously submitted budget documents. The Program Manager issues, in writing, overall guidance regarding the allocation of funds to the various research projects, program initiatives and performing activities for the coming year. This guidance is approved by CNO-N773 and the SEA 00C, and the researcher is notified.

b. Funds are delivered from SEA 00C1 to the NEDU Comptroller for disposition in accordance with the approved guidance from the Program Manager. Authority for release of funds in this account from the NEDU is restricted to the Program Manager, the Director of Diving Programs, and the Supervisor of Diving. Separate, independent, identifiable and traceable lines of accounting will be maintained by the NEDU Comptroller in support of PE 0603713N, and approved by the Program Manager. Audits of this accounting line will be conducted concurrently in conjunction with other regularly scheduled SEA 00C and NEDU audits.

8. Progress Reviews

a. The Program Manager will conduct one or more face-to-face individual progress reviews with each performing Principal Investigator every year, and hold a combined overall program review with all performers annually.

b. The Program Manager will brief SEA 00C at least each quarter on program progress.

9. Reports

a. Principal Investigators will be responsible for providing Incremental Reports and Completion Reports to the Program Manager using the schedules and formats in enclosures (5) and (6).

JAMES R. WILKINS, III

Distribution: (See next page)

Distribution:
SEA 00CN
SEA 00CNA
SEA 00CM
CNO-N773
CNO-N775
BUMED-M3F7
BUMED-M2
ONR-341
NAVXDIVINGU

EXAMPLE

00CN
Ser 001
--/--/-

From: Program Manager, Deep Submergence Biomedical Development
To: Technical Advisory Board (Attn: *members*)

Subj: REVIEW OF DEEP SUBMERGENCE BIOMEDICAL R&D PROPOSALS

Encl: (1) BAA excerpt
(2) Proposals (n=x)
(3) Contact information for board

1. Thank you very much for agreeing to serve on the advisory board. The board's charter is to: a) provide technical advice on the scientific merit, cost, and feasibility of the pre-proposals, and b) assist in structuring an efficient program to accomplish the goals. As discussed previously, request that your membership on this board remain close-hold until deliberations are complete.

2. Enclosure (1) is an excerpt from this program's most recent Broad Agency Announcement (BAA), which outlines the topics requested and products desired. In FY-*XX*, there is approximately $*XXXk* of Deep Submergence Biomedical Development resources, which are available for re-programming. We are interested in: a) employing the best at fair cost; b) fostering collaborative efforts among facilities; c) bringing new talent into the program, and most importantly, **obtaining useful high quality products on time**.

3. Enclosure (2) contains the proposals. This material is proprietary and / or privileged information and must not be communicated outside this advisory board process. I request that all materials be returned to me when the review process is complete. A simple evaluation form is included at the beginning of every proposal attachment, and I request that this form be completed for every proposal. Additionally, it would be of

great help if you would offer written options on how to coordinate the various proposed experiments into an efficient collaboration. We will have the opportunity to discuss this later in more depth at our meeting. Please feel free to discuss any issues among yourselves, enclosure (3).

4. Advisory Board process and schedule:

(date):	BAA published
(date):	Pre-proposals received from submitters
(date):	Pre-proposals accepted for full proposal development, or rejected
(dates):	Program Review, (location)
(date):	Full proposals received from submitters
(date):	Proposals sent to Technical Advisory Board
(date):	Technical Advisory Board meeting
(date):	Final decision by NAVSEA and N773

5. Please contact this office with any questions or issues, at 202-781-4361, DSN 326-4361, e-mail schwartzhj@navsea.navy.mil. Mrs. Lisa Williams is the program assistant, and will help expedite and track our efforts. She can be reached in Panama City at 850-230-3205, e-mail: Williamslm@nedu.navsea.navy.mil.

H.J.C. SCHWARTZ
By direction

Copy to:
CNO-N773
NAVSEA OOC3
NAVSEA OOC3B
CO (member's command)

PREPROPOSALS

Purpose: To describe the PI's initial R&D concept, facilitate preliminary discussion with SEA OOCN, determine the appropriate funding category, verify the Navy need for the work, and allow preliminary technical review before major time and effort are spent on developing a full proposal.

Use for: New work and follow-on work to a completing work unit.

When: Submit at anytime. Preproposals for projects to start on 1 Oct must be received by (date)

Length: 3-5 pages

Copies: 2 paper copies; 1 electronic copy

Submit to: Lisa Williams, Program Assistant
Navy Experimental Diving Unit
321 Bullfinch Road
Panama City, FL 32407-7015
E-mail: williamslm@nedu.navsea.navy.mil
Telephone: 850-230-3205
Fax: 850-230-3123

Format:

1. Date prepared:

2. Title of project:

3. Principal investigator:
   Degree(s):

4. Position title (if any):
Organization:
Department:
Phone number (commercial):
(DSN):
FAX number (commercial):
(DSN):
E-mail address:

5. Dates of entire work unit period:

6. Resources:
a. Funds ($K) required for each fiscal year and total funds ($K):

Item	**Year 1**	**Year 2**	**Year 3**
In-House Personnel			
Equipment and Maintenance			
Expendable Supplies			
Animal Purchase and Per Diem			
Travel			
Miscellaneous			
Contracts/Consultants			
Indirect/Overhead			
Total:			

b. Personnel required for each fiscal year (professional and supporting, military and civilian). Indicate percent effort for each person.
c. Major equipment required for each fiscal year (indicate whether it is available
or will be purchased, the expected year of purchase, and the projected cost).

7. Navy need:
a. State the Navy need or deficiency.
b. Explain how the preproposal addresses the need.
c. List any official requirement documents that support the need. (Documents should be current. SEA OOCN can assist.)

8. Specific aims:
a. Describe the research hypothesis to be tested or the item to be developed.

b. Describe any associated, anticipated product(s).

9. Experimental design and methods:

a. Describe how the work will be carried out, stepwise to the final product. This section should provide sufficient detail so a knowledgeable reviewer can judge whether the approach is reasonable and complete.

b. Explain the rationale for the approach, relative to other approaches that could be taken.

c. Identify key associate investigators (by name, if possible) and the research contribution expected from each.

10. Assessment of risk:

a. Discuss the perceived level of risk of the research (high, medium, low). Are there any special considerations (i.e., new technological opportunities) that especially support investing in this R&D effort at this time?

b. Discuss any known problems that could inhibit the success of the R&D effort, and factors, which contribute to research risk.

11. Related activities:

a. Identify any other group's (government or civilian) performing similar R&D efforts.

b. State whether DTIC and civilian (i.e., Medline) literature searches have been conducted.

c. Discuss any plans for interacting with other groups to maximize the likelihood of state-of-the-art results.

12. Transition approach:

a. Describe how the research product(s) would transition to use by the Fleet.

b. Describe any interactions with a Fleet user or transition sponsor.

c. Estimate how long it would take to achieve the transition product.

13. Literature cited:

Cite the five most pertinent, recent references from the scientific literature.

14. Suggested reviewers:

a. Names, organizations, and phone numbers of reviewers especially well qualified to review the preproposal.

b. Names and organizations of reviewers preferred not review the preproposal (optional).

DEEP SUBMERGENCE BIOMEDICAL DEVELOPMENT PROGRAM

Proposal Format

Enclosure (3)

PROPOSALS

Purpose: To provide a complete description of the R&D effort from start to finish, for each year of funding. The yearly work plan, milestones, budget, personnel, etc., are provided in detail for the first year and in summary for the out years (details for the out years will be supplied on subsequent incremental reports).

Use for: After pre-proposal approval, for new work, and for follow-on work to an ending work unit.

When: Years refer to fiscal years.

Length: 12 - 14 pages; appendices (required curricula vitae and optional attachments may exceed the 14 page limit).

Copies: 1 paper copy; 1 electronic copy.

Submit to: Program Manager, Deep Submergence Biomedical Development Program (NAVSEA OOCN).

Format: In the body of the proposal, include each section, noting any sections that are not applicable. The length of each proposal section should be governed by the completeness necessary for a full discussion of the specific topic.

INSTRUCTIONS

1. PROPOSAL COVER SHEET

- **TITLE**: The title of the proposal should not exceed 240 characters and spaces; it should be informative and indicative of Naval/Marine Corps relevance if possible; and it should avoid the inclusion of symbols, acronyms, and mathematical or scientific notation.

- **PROPOSAL NUMBER**: Leave blank. NAVSEA OOCN will assign this number.

- **PRINCIPAL INVESTIGATOR**: Provide the name of the principal investigator, rank, corps, service, and degree(s).

- **MAILING ADDRESS:** Provide the mailing address of the principal investigator including laboratory, department and subdivision designations.

- **E-MAIL ADDRESS:** Include the E-mail address for the principal investigator.

- **PHONES:** Include commercial and DSN telephone numbers for office and facsimile phones of the principal investigator.

- **USE OF HUMAN SUBJECTS:** If the work plan in any year involves using human volunteers (including human-derived materials or data that contain personal identifiers), indicate "YES" and provide the estimated number to be used. If human subjects or personally identifiable material or data are not to be used, indicate "None".

- **USE OF ANIMALS:** If animal work is planned, indicate by listing each animal species to be used by common name, such as mice, rats, rabbits, etc., and provide the estimated number of each species to be used. If animal work is not planned, indicate "None".

- **INVESTIGATIONAL DRUGS, DEVICES, OR BIOLOGICS:** If human volunteer studies are planned that use an investigational drug, device, or biologic, indicate the drug or biologic's name, and manufacturer or supplier. If no investigational drugs or biologics are used, indicate "None".

- **PERSONNEL/ENVIRONMENTAL HAZARDS:** If the proposed studies involve any procedures, materials, chemicals, microbiological organisms, or situations that produce personnel or environmental hazards beyond potential routine laboratory exposures (and, therefore, require special precautions) indicate "Yes" and note the specific hazard. If unusual hazards are not evident, indicate "None".

- **PROPOSED START DATE:** Indicate the preferred start date for the R&D effort. Proposals may be submitted for evaluation and funding consideration any time during the year, so new start dates need not necessarily begin on 1 October to coincide with the start of the federal fiscal year.

- **PROPOSED BUDGET:** Summarize the direct and indirect costs of the proposed research for each year of the project. Proposal submissions generally are for one to three years.

- **SIGNATURES AND DATES:** The cover sheet must be signed and dated by the principal investigator and also by the laboratory Commanding Officer for military laboratories. These signatures must follow the statement:

"I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports and agreed upon products to NAVSEASYSCOM.

- See example of TITLE page on page 5.

2. TABLE OF CONTENTS.

- See example on page 7.

3. BODY OF PROPOSAL. The body of the proposal has the following sections.

   Section A: PROJECT SUMMARY
   Section B: PROJECT DESCRIPTION
   Section C: LITERATURE SEARCHED
   Section D: RESOURCES REQUIRED
   Section E: OTHER SUPPORT
   Section F: ENVIRONMENT
   Section G: APPENDIX

EXAMPLE OF PROPOSAL

TITLE: Enhanced Submarine Escape and Rescue

PROPOSAL NUMBER:

PRINCIPAL INVESTIGATOR: John J. Researcher, LCDR, MSC, USN

MAILING ADDRESS: Naval Submarine Medical Research Laboratory
Biomedical Sciences Department
Box 900
Groton, CT 06349-5900

E-MAIL ADDRESS: Researcher@nsmrl.navy.mil

TELEPHONES: Office: (860) 694-1234 DSN 694-1234
Facsimile: (860) 694-1111 DSN 694-1111

BUSINESS OFFICE POINT OF CONTACT: Mrs. J. Comptroller

Phone: (860) 694-1234
GOV'T AUDITOR POINT OF CONTACT: Mr. A. Careful
Phone: (860) 694-1234

USE OF HUMAN SUBJECTS: Yes Number: 18

USE OF ANIMALS: None

INVESTIGATIONAL DRUGS, DEVICES, OR BIOLOGICS: None

PERSONNEL/ENVIRONMENTAL HAZARDS: None Hazard: NA

PROPOSED START DATE: 1 October 2003

PROPOSED BUDGET: Year 1 Year 2
Year 3
Direct Costs:
Overhead Costs:
Total Costs:

I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports and agreed upon products to NAVAL SEA SYSTEMS COMMAND.

SIGNATURES AND DATES:

_____ _____

John J. Researcher Date Commanding Officer Date

TABLE OF CONTENTS

Page

Proposal CoverSheet 1
Table of Contents 2

Section A: PROJECT SUMMARY

Abstract 3
Key Personnel Summary x
Budget Summary x

Section B: PROJECT DESCRIPTION

Aims/Objectives x
Background and Significance x
Naval/Marine Corps Relevance/Operational Use Scenario x
Preliminary Work x
Experimental Design and Methods x
Milestones x
Research Transition Plan x
Patent Disclosures and Inventions x

Section C: LITERATURE SEARCHED

Bibliography x
DTIC and Civilian Databases x
Keywords x

Section D: RESOURCES REQUIRED

Detailed Budget x
Equipment Purchase and Maintenance x
Personnel and Organization x
Contracts, Consultants, Collaborators, Consortia x

Section E: OTHER SUPPORT x

Section F: ENVIRONMENT

Facilities x
Personnel and Environmental Hazards/Precautions x

Section G: APPENDIX

Curricula Vitae (required) x
Other (optional) x

SECTION A: PROJECT SUMMARY

ABSTRACT

- The abstract should provide a complete, succinct, and accurate description of the proposed work. It should stand alone and be separable from the rest of the proposal. The abstract should be the only entry on page 1 of the proposal.

- Use layman's language.

- Avoid summaries of past accomplishments and the use of the first person (I, we).

- Briefly describe:

- The problem or issue addressed by the proposal;
- The broad, long-term objective(s);
- The hypothesis (es) or specific aim(s);
- The experimental design and methods for accomplishing the goal(s) of the study (for multi-year projects, succinctly identify what portion of the study will be completed in each year);
- The product(s) to be delivered upon completion of the R&D effort;
- The contribution of the product to science at large;
- The contribution of the product to easing a Navy need or deficiency.

KEY PERSONNEL SUMMARY

NAME, RANK/DEGREE	POSITION, TITLE or ROLE*	DEPARTMENT or ORGANIZATION**

*PI = Principal Investigator; CPI = Co-Principal Investigator (if PI is from another facility); AI = Associate Investigator

**Indicate if any key individual is a post-doctoral fellow, an IPA, a visiting scientist, etc.

BUDGET SUMMARY

BUDGET ITEM (Use gov't fiscal year 1 Oct-30 Sep)	1st Yr $ (FY__)	2nd Yr $ (FY__)	3rd Yr $ (FY__)
In-House Personnel			
Equipment and Maintenance			
Expendable Supplies			
Animal Purchase and Per Diem			
Travel			
Miscellaneous			
Contracts/Consultants			
TOTAL DIRECT COST:			
TOTAL OVERHEAD COST:			
GRAND TOTAL COST:			

SECTION B: PROJECT DESCRIPTION

AIMS/OBJECTIVES

- Provide a concise statement of the problem or issue addressed by the proposal and the major objective(s) of the proposal.

- Describe the hypothesis(es) to be tested, and each specific aim of the proposal.

- Clearly define the product(s) to be delivered upon completion of the R&D effort.

BACKGROUND AND SIGNIFICANCE

- Demonstrate a comprehensive understanding of the literature by ensuring adequate citation of references regarding key scientific points (use the citation format specified in Section C).

- Describe previous research endeavors that led to the proposed aims and scientific questions.

- Critically evaluate existing knowledge noting any major discrepancies, inaccuracies, and controversies in the literature to demonstrate your comprehensive view of the subject.

- Clearly identify knowledge gaps that the proposed effort is intended to fill.

- Include specific points that demonstrate the originality and innovativeness of the proposed research.

- State the importance of the proposed work by relating the specific aims of the project to longer-term research objectives and clinical applications to which the proposed research could lead.

- Clearly indicate whether the research is likely to produce new data, techniques, concepts, products, or confirmation of an existing hypothesis(es).

NAVAL/MARINE CORPS RELEVANCE/OPERATIONAL USE SCENARIO

- Describe the specific Naval/Marine Corps relevance for the proposed work or its potential product outcome.

- Discuss the technical or clinical significance of the proposed work in terms of demonstrating improvement of existing procedures or standards for specific operational scenarios, needs, or difficulties.

- Cite tasking letters or relevant requirements documents. Copies may be included in the Appendix.

PRELIMINARY WORK

- Provide information on any preliminary, relevant studies conducted primarily by the principal investigator demonstrating the investigator's experience and competence in the proposed area of study; preliminary study data should be discussed to demonstrate the feasibility of the proposed research effort, and the importance of the new data, concepts, or techniques evident in the preliminary studies.

- Submit any figures or diagrams depicting relevant preliminary study data, here or in the Appendix.

- Include titles and complete reference citations for relevant completed work by the involved investigators directly supporting the proposed research; copies of relevant preliminary manuscripts or papers submitted for publication should be included in the Appendix.

- Use this section to report any progress or accomplishments in related research previously funded by this office that may serve as support documentation for continued research funding in the new proposed area.

EXPERIMENTAL DESIGN AND METHODS

- Disciplined up-front thought should be given to planning the entire research and development effort from beginning to product delivery.

- The narrative must provide the planned experimental design for each year the proposal is to be funded. Each year's discussion should be introduced under a heading:
    - "Detailed Work Plans for Year 1"
    - "Detailed Work Plans for Year 2"
    - "Detailed Work Plans for Year 3", etc.

- Describe the experimental design, methods, and procedures to be used to accomplish <u>each specific aim</u> of the proposed research study.

- Include the means by which the data will be collected, analyzed, and interpreted.

- Outline any new methodology to be used and its advantage over existing methodologies.

- Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the specific aims.
- In general, planned procedures should be demonstrated to be feasible, adequate, appropriate, and as innovative as possible for the proposed research.

- If the experimental design involves special protocols (involving the use of human subjects, vertebrate animals, or investigational drugs, devices, or biologics; or unusual personnel/environmental hazards), sufficient information must be included in the proposal to convince the technical reviewer of the appropriateness of the work plan. Issues would include the kind and number of animals/volunteers, sex, weight, age range; the need to use the specific species and alternatives considered; the statistical methods used to determine that the numbers of animals to be used are necessary to achieve scientific validity of the data.

- Technical approval of the proposal and movement of funds into the principal investigator's account at the laboratory <u>does not</u> constitute approval to execute special protocols in the categories listed above. Before such protocols are begun, all related documentation (applications and approvals) must be resident in the NAVSEA OOCN work unit master file. For convenience, pertinent instructions are listed:

- Use of Human Subjects

- Reference: SECNAVINST 3900.39C
  Requires: Approval by the institution's Committee for the Protection of Human Subjects (CPHS), the CPHS convening authority, and the applicable approving authority.
  Notes: Human use includes the use of human subjects, data obtained from individuals, questionnaires, or identifiable private information, the use of approved drugs or licensed biologics in a manner that varies from the "Indications and Usage" or "Dosage and Administration" sections of the current package insert. The "practice of medicine" exclusion for unlabeled use of drugs or biologics does not apply to research.

- Use of Animals

  Reference: SECNAVINST 3900.38B
  Requires: Approval by the institution's Animal Care and Use Committee.

- Use of Investigational Drugs, Devices, or Biologics

  Reference: BUMEDINST 6710.4 or its current version.
  Requires: FDA approval

- Unusual Personnel/Environmental Hazards

  Reference: Title 29 Code of Federal Regulations Chapter 1910
  Requires: Approval of laboratory Safety Committee

DELIVERABLES

- Provide a Statement of Work (SOW) for each year describing the deliverables, when they are due, what type they will be, e.g. report, prototype, etc.

MILESTONES

- Provide a milestone chart that shows quarterly milestones by fiscal year, for each year the proposal is to be funded. The chart should convey the flow of the work over time, showing any dependencies that exist among sub-efforts. Products projected

for delivery at specific time points should be identified.

- The milestone chart should be "read along" with the work plan narratives and should reflect a level of effort consistent with the level of funding requested for each year.

- The following page shows the milestone chart format:

MILESTONE DESCRIPTION	*1st Yr FY03*				*2nd Yr FY04*				*3rd Year FY05*			
	1	2	3	4	1	2	3	4	1	2	3	4
A. Subproject A. Short Title:												
1) Milestone A.1. description		S	C									
2) Milestone A.2. description			S	C								
3) Milestone A.3. description			S	C								
4) etc.				C								
B. Subproject B. Short Title:												
1) Milestone B.1. description			S	→	C							
2) Milestone B.2. description			S	→	C							
3) Milestone B.3. description				S	→	C						
4) etc.												
C. Subproject C. Short Title:												
1) Milestone C.1. description						S	→	→	R			

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

*FOR THOSE WHO ARE NOT FAMILIAR WITH EDITING CHART, SIMPLY CLICK TO THE LEFT OF LETTER, OR SYMBOL TO HIGHLIGHT. ONCE BOX HAS BEEN HIGHLIGHTED YOU CAN COPY (Ctrl+C) AND PASTE (Ctrl+V) TO ANOTHER AREA.

PROJECT # and Short Title:

MILESTONE DESCRIPTION	1st Yr FY 1 2 3 4	2nd Yr FY 1 2 3 4	3rd Yr FY 1 2 3 4	etc. FY 1 2 3 4
A. Subproject A. Short Title:				
1. Milestone A.1. description	S----------C--R			
2. Milestone A.2. description		S----------C--R		
3. Milestone A.3. description				
4. etc.				
B. Subproject B. Short Title:				
1. Milestone B.1. description				
2. Milestone B.2. description				
3. Milestone B.3. description				
4. etc.				

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

RESEARCH TRANSITION PLAN

- New research information, technical capabilities, and preliminary products are often not optimally presented or configured as development products for transition to operational Naval and Marine Corps forces or medical support units; therefore, describe as clearly and realistically as possible the relevant next steps that should be followed, pending successful achievement of your research aims, to proceed along a pathway for eventual research information and product transition to the operational forces.

- Describe your contact with specific Naval/Marine Corps operational units that demonstrates your ongoing awareness of operational needs and your ability to be involved in eventual transition, support, and testing of your new research information, technical capability, or developmental product in an operational environment.

PATENT DISCLOSURES AND INVENTIONS

- Describe any patent disclosures or inventions that already exist which may bear on the ultimate licensing or delivery of technology or products developed under this proposed research project.

- Briefly outline any potential patent or invention opportunities that may be anticipated with successful completion of this proposed research.

SECTION C: LITERATURE SEARCHED

BIBLIOGRAPHY

- List all references cited in the proposal, in order of appearance in text. Provide the complete citation for each reference. In the body of the text use reference numbers only. Examples (in text): "Several research studies have shown that no deleterious effects from the procedures have occurred (2,8,17,19)."

- Make a judicious attempt to compile a relevant and current list of literature citations; it need not be exhaustive. A complete citation for each reference is required and includes the names of all authors, the title of the article or chapter,

the name of the journal or book, volume number, page number, and year of publication (and for books, the city and publisher). Use a consistent format throughout.

- Information in the body of the proposal should be appropriately referenced as in any journal article; uncited references should not be included in this section.

Example of Journal:
#. Author(s). Title. Journal, year; volume number(number):pages.

4. Cockburn WC, Drozdov SC. Poliomyelitis in the World. Military Medicine, 1970; 42(3):405-17.

Example of Book Chapter:
#. Author(s). Title. In: Editors (Eds.), Title of book, publisher's city & state: name of publisher, year: pages.

5. Cockburn, WC. Poliomyelitis in the World. In: Poon LW (Ed.), Medicine in the World. Washington, DC: Alcott & Barnes, 1970:215-33.

Example of Technical Report:
#. Author(s). Title, City/State: publisher; year, Report No.

3. Birney AJ, Hall MM. Early Identification of Children with Written Language Disabilities, San Diego (CA): Naval Health Research Center, 1961, Report No.81-15.

- Be sure to cite any related work at other NAVSEA OOC funded activities or in the NAVSEA OOC contract program and to describe any links and collaborations.

DTIC AND CIVILIAN DATABASES

- Perform a Defense Technical Information Center (DTIC) search and civilian literature search (e.g. Medline) to identify any related research previously performed or ongoing within the DoD.

- Complete and include this statement: "A DTIC search(es) was(were) performed, dated _____. The proposed work will not result in any undue duplication of technical effort previously performed by other organizations. There were ____ finds.

- If the DTIC search did find related work within the DoD, describe how the finds relate to the proposed work and why the proposed work still should be done.

- Abstracts of such finds should be included in the Appendix; if the DTIC search produced no finds, the search documents should not be submitted with the proposal, but should be retained by the investigator.

KEYWORDS

- Scientific/Technical: List approximately 10 scientific or technical keywords that best support the search for similar and related research work through standard scientific publication databases; examples: diving; submarine escape; CO_2 scrubbing; decompression sickness; bends.

SECTION D: RESOURCES REQUIRED

YEAR ONE

DIRECT COSTS

DIRECT LABOR:
(Example below)

IN-HOUSE PERSONNEL TOTAL DIRECT LABOR COST $80,000

Details of direct labor cost

Professional	Accelerated Salary ($)/Yr*	Effort (% Man-Yr)**	Total ($)/ Yr
CAPT Joan E. Doe, MSC USN	$0	40%	0
Edward C. Davis, M.D.	$100,000	30%	30,000
Bruce W. Williams, PhD.	$120,000	25%	30,000
Support			
John R. Doe, GS-5	$40,000	50%	20,000

* Accelerated salary includes actual salary plus fringe benefits. For those personnel who will not be paid directly via this proposal (e.g., military), enter 0 in the "Total ($)/Yr" column.
**Effort is the total amount of this person's time that will be spent on this project.

OTHER DIRECT COSTS (ODC):
(Example below)

EQUIPMENT PURCHASE AND MAINTENANCE ($): $35,000

Centrifuge	20,000
Maintenance Contract, Cell Sorter	11,000
Describe Item	2,000
Describe Item	2,000

EXPENDABLE SUPPLIES ($):	Cost
Major Item Group 1	Cost
Major Item Group 2	Cost
Major Item Group 3	Cost
Other	Cost

NOTE: Provide major items (by category if possible); estimate minor items under "Other".

ANIMAL PURCHASE AND PER DIEM ($):		Cost
Purchase 200 rats	Cost	
House 25 rabbits	Cost	
Describe Item	Cost	
Describe Item	Cost	

TRAVEL ($):		Cost
(To include airfare, per diem day, etc.)		
American Society for Microbiology Annual Meeting	Cost	
Centers for Disease Control Coordination Meeting	Cost	
NAVSEA Program Review	Cost	
Describe Trip	Cost	

MISCELLANEOUS ($):		Cost
Hyperbaric Chamber Support	Cost	
Machine Shop Support	Cost	
Describe Item	Cost	
Describe Item	Cost	

SUBCONTRACTS/CONSULTANTS/COLLABORATORS ($):			Cost
Organization	Type	Cost	
University of Texas	Contract	Cost	
George Washington University	IPA	Cost	
Geo Centers, Inc.	Task Order	Cost	
Jackson Foundation	Grant	Cost	
Naval Health Research Center	MIPR	Cost	
Describe Item		Cost	

TOTAL DIRECT COSTS: $

INDIRECT COSTS / OVERHEAD

CATEGORY	RATE (%)	COST
LABOR (e.g. $80,000 X 0.3)	30%	$24,000
EQUIPMENT PURCHASE AND MAINTENANCE (e.g. $35,000 X 0.1)	10%	$3,500
EXPENDABLE SUPPLIES	%	$
ANIMAL PURCHASE AND PER DIEM	%	$

TRAVEL	%	$	
MISCELLANEOUS	%	$	
SUBCONTRACTS / CONSULTANTS	%	$	
TOTAL INDIRECT COSTS			**$_____**
TOTAL DIRECT PLUS INDIRECT COSTS			**$_____**
FIXED FEE (%_____)(If used by your institution)			**$_____**
GRAND TOTAL			**$_____**

- Include a statement on the effect of a 20% increase or decrease in funding in the execution year. This section should discuss how additional funds would be used, and what additional milestones would be reached. In the case of funding cuts, list the specific milestones that would slip, and whether personnel reductions would be necessary.

YEAR TWO
Similar to above

YEAR THREE
Similar to above
Etc.

EQUIPMENT PURCHASE and MAINTENANCE

- Provide a justification for all equipment requested.

PERSONNEL and ORGANIZATION

- Describe the research expertise and the specific research role of each investigator named in the proposed effort.

- Briefly outline the coordination plan for bringing together the various investigators from different disciplines or departments within the laboratory or from different institutions. Discuss any formal plans or arrangements that have been made for coordinating the research efforts and ensuring that appropriate time, direction, and research focus is brought to bear on the project over the projected course of the research.

CONTRACTS, CONSULTANTS, COLLABORATORS, CONSORTIA

- Describe the role and provide justification for all on-site contractors, including all on-site contract professional and support personnel requested.

- Describe the research efforts to be performed by off-site contractors in support the overall project goals.

- Describe the role of off-site co-investigators/collaborators involved in the project. Indicate if, and how, these co-investigators/collaborators will be paid from the requested funds (e.g. No Cost, Purchase Order, Contract, MIPR, etc.). For large joint ventures between two or more organizations, provide a separate detailed budget exhibit for each organization showing the biomedical RDT&E funds specifically requested from NAVSEA 00CN and the supporting funds requested/expected from other sponsors. Provide letter for supporting organization(s) agreeing to the joint venture.

- List any individuals, including addresses and phone numbers, expected to provide scientific consultation, outside expert advice, or other consultative support to the project.

SECTION E: OTHER SUPPORT

- Describe any current, pending, or planned research funding support that specifically contributes to the proposed research effort.

- For each item of support, list the title of the research proposal, the principal investigator, the funding amount received or anticipated, and program element/project/task numbers if available.

SECTION F: ENVIRONMENT

FACILITIES

- Describe any special facilities and equipment other than standard laboratory facilities and equipment necessary for performing the proposed research.

- Describe any equipment or facilities necessary for the

research but unavailable at the in-house laboratory, and plans to meet these needs using facilities and equipment at other laboratories.

- List all performance sites for the planned research including collaborations, contracts, and sites that may be included only for animal care facilities.

PERSONNEL AND ENVIRONMENTAL HAZARDS/PRECAUTIONS

- Describe any proposed procedures, materials, chemicals, infectious organisms, or situations that produce personnel or environmental hazards beyond potential routine laboratory exposures and require special precautions.

- Describe the precautions being taken to prevent any personnel and environmental hazards that may potentially occur.

SECTION G: APPENDIX

CURRICULA VITAE

- Include current curriculum vitae for each principal, co-principal, or associate investigator participating in the research. All key in-house personnel and on-site contract personnel should be included.

OTHER

- Include abstracts, publications, preprints, and graphic data to support preliminary research findings or related research work performed by the investigators listed in the proposal.

- Include any information or address any issues not covered in the various proposal sections that the investigators feel NAVSEA OOC should be aware of during the evaluation of the proposal submission.

DEEP SUBMERGENCE BIOMEDICAL DEVELOPMENT PROPOSAL EVALUATION FORM

FY-03

Project Title:
Principal Investigator:

a. Give a numerical score for the three questions below, using the following 10-point scale:

POOR: 1-3 FAIR: 4-5 GOOD: 6-8 EXCELLENT: 9-10

1. What is the scientific merit of the proposal? Please consider:

Is the hypothesis clear and sound?

Is the objective/purpose well delineated?

Is the background appropriate?
Is the approach/experimental design well laid out?
Is the methodology sound and state-of-the-art?
Is the work plan appropriate?
Is the work innovative?

Comment:	**SCORE**

2. What is the probability of success of this proposal? Please consider:

Is the principal investigator capable of performing the work? (Based on his/her publications; described past work experience;

references showing familiarity with recent, pertinent work of other groups)
Can the work be accomplished with the resources described? (Consider time, funding, and personnel)
Is the project basically doable?

Comment:	**SCORE**

3. What is your overall impression of this proposal?

Comment:	**SCORE**

b. Please comment on the technical quality of the proposal (attach additional pages if necessary). Please address any specific technical strengths or weaknesses, and why you recommend funding or not funding.

Comment:	**SCORE**

c. Please rate your familiarity with the science area addressed in this proposal: (check one)

Have specific knowledge or past experience in this area. ☐
Have general knowledge or past experience in this area. ☐
Have minimal qualifications to evaluate this proposal. ☐
Do not feel qualified to evaluate this proposal. ☐

d. Conflict of Interest Statement:

By my signature below, I attest that I have no professional or personal interest that would in any way influence my ability to review this proposal objectively. I am not involved in the preparation or execution of this proposal, and have no interest in the final decision to fund or not to fund the work.

e.	**Evaluator Name:**

f.	**Date Completed:**

INCREMENTAL REPORTS

Purpose: 1. To describe work unit accomplishments or issues for a defined reporting period only (usually the previous six months). *This is not a cumulative report;* information provided in previous reports should not be repeated. All incremental reports will be added to NAVSEA OOCN's master file of the work unit.

2. For June Incremental Reports Only: Details of the work plan, milestones, budget, and other resources required for the upcoming fiscal year, not provided in the original proposal, should be included. These details should be to the level of those called for in the proposal and appropriate pages from the proposal format should be used. The total budget for the upcoming year should not exceed the amount shown in the original proposal for that year unless previously negotiated with SEA OOCN (any such negotiation should occur as soon as possible as budget plans begin to be fixed about one year before funds are available).

Use for: All NAVSEA OOC work units.

When: Every January 31 and June 30. Should either date be on a weekend, then submit it on the following weekday. For a new research project, no report is necessary within the first 90 days of beginning. For a research project concluding within 90 days after an incremental report due date, a final report is required and no incremental report will be necessary.

Length: 1-2 pages (attachments may exceed the recommended page limit).

Copies: Submit by E-mail as an attachment; or alternatively, original document on paper and on disk.

Submit to: Lisa Williams, Program Assistant
Navy Experimental Diving Unit
321 Bullfinch Road
Panama City, FL 32407-7015
E-mail: williamslm@nedu.navsea.navy.mil

Format:

INCREMENTAL REPORT - (Date Due)

TITLE:

PRINCIPAL INVESTIGATOR:

INSTITUTION:

REPORTING PERIOD: (e.g. 30 Jun 2001 - 31 Jan 2002)

AWARD PERIOD: (e.g. 4 Jan 2000 - 30 Sep 2002)

MILESTONE STATUS

- State that the milestone is "on schedule" or
- State that the milestone is "changed" and
- Give the new start date, completion date, transition date, etc.
- Give the reason(s) for the milestone change.

ACCOMPLISHMENTS:

- A concise statement (3 lines maximum) of the noteworthy progress accomplished under the 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.

- 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.

Milestones under which no significant progress was made during the reporting period should be listed and the entry should be "none". All active milestones should be addressed in the report. Since the reading audience will be sponsors, research

managers, and other interested parties (not technical experts), use layman's language and clear writing.

ISSUES: Discuss anything SEA OOCN should know to assist, promote or protect the work unit. Any proposed revision of the original process, with rationales, should be provided. Approval or disapproval of suggested revisions will be noted by SEA OOCN and communicated back to the PI. The annotated report will be entered in NAVSEA OOC's master work unit file so that the evolution of the work unit over time will be documented.

PROBLEMS: Discuss any issue that is a problem requiring help from SEA OOCN or higher authority.

PRODUCTS: Provide citations for the following work unit products, by category:

a. Journal publications
b. Technical Reports
c. Letter Reports to Fleet Users
d. Presentations and Abstracts
e. Patents
f. CRADAs

Journal article citations should be complete and should be written in the following style (Vancouver style):

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 a publication is listed as "in press," the PI should provide the complete citation in the next incremental or summary report.

ATTACHMENTS:

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.

COMPLETION REPORT

Purpose: To describe cumulative work unit accomplishments from the beginning of a work unit to its conclusion.

Use for: All in-house work units and extramural contracts.
When: Three months after the work unit ends.
When: Final Completion Report is due no later than the completion date of the work unit or contract. Ensure your proposal takes this time into account when considering the period of performance.

Length: 5-10 pages (attachments may exceed the recommended page limit).

Copies: 2 paper copies; 1 disk copy

Submit to: Original documents to NAVSEA OOCN.

Format: Note that, in most part, this report consolidates the incremental reports.

1. Context: Briefly describe the specific aim/objectives and the experimental methods used (if a research study, include the specific hypothesis tested).

2. Narrative: Describe the significant results achieved during the entire funding period and explain why these findings are important. 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. Such publications should be attached if not submitted in any previous report. Since the reading audiences will be sponsors and research managers and other interested parties, layman's language and clear writing should be emphasized.

3. Products: Provide citations for the following work unit products, by category:

a. Journal publications
b. Technical reports
c. Letter reports to Fleet users
d. Presentations and Abstracts
e. Patents
f. CRADAs
g. Awards

Journal article citations should be complete and should be written in the following style (Vancouver style):

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 products are pending (publication "in press", etc.) at the time of the final report, the PI s must provide the NAVSEA OOCN the finished products at a later date, for inclusion in NAVSEA's master file of the work unit.

4. Transitions: If the work resulted in follow-on research or development, cite the program element and project receiving the transition, and the start year, end year, and estimated first year funding.

5. Appendix: Attach copies of journal publications, technical reports, abstracts, or pre-prints 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.