Proposal Considerations for Contracting

I. Government Personnel & Their Roles
II. Human Subject Research
III. Animal Use
IV. Intellectual Property
V. SOW, deliverables and Milestones
# DARPA Tech Office vs. Agent

<table>
<thead>
<tr>
<th>Ability</th>
<th>DARPA Tech Office</th>
<th>Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issues solicitations</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Proposal receipt and scientific review</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Source of funding</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Contract* negotiation and award</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Technical and financial oversight once project is underway</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Issues contract* modifications</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>Authority to approve changes to project tasking, schedule, and budget**</td>
<td>✗</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Note: the term "contract" is used as a catch-all for any type of award instrument (including, but not limited to cooperative agreements, contracts, and other transactions)*

**Note: although the agent contract officer has ultimate authority to change the contract, the DARPA PM and SETA team is still very involved in the process*

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Government Personnel and Their Roles

**DARPA:** Sponsor -- Dr. Amy Jenkins
- Solicits proposals
- Selects projects for funding
- Provides funds to NIWC Pacific for Contract or Grant Negotiation and Award
- Provides total program oversight

**DARPA SETAs**
- *Financial/Program Support* -- Shawn Rich
- *Technical Support* -- NOW Technical SETA Team

**NIWC Pacific:**
- *Contracting Officer’s Representative (COR)* -- Dr. Patrick Sims
- *Financial* -- Amy Nehrich, Lauren Carlson
- *Human Research Protections Official* -- Dr. Kara Sorensen
- NIWC contracts department awards the Contract or other agreement
- Navy lab funded by DARPA to provide both contract Administration and Technical oversight of your project

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Human Subject Research Definition

32 Code of Federal Regulations (CFR) Part 219.102:

**Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Human Subject**: A living individual about whom an investigator (whether professional or student) conducting research obtains:
– (1) Data through intervention or interaction with the individual OR
– (2) Identifiable private information (see 45 CFR Part 46.102),

Exempt or Not Human Subjects Research Determination (needs IRB/Chair determination AND needs HRPO concurrence)
DEPARTMENT OF DEFENSE (DOD) REGULATIONS AND GUIDANCE and DON SPECIFIC REQUIREMENTS

- The Belmont Report
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- Title 10 United States Code Section 980 (10 USC 980), “Limitation on Use of Humans as Experimental Subjects”

- DoD Instruction (DoDI) 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research”
- DoDI 3210.7, “Research Integrity and Misconduct”
- DoDI 6200.02, “Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs”

- SECNAVINST 3900.39E (Specific to Service (Air Force and Army have own instruction))

* Revisions to DoD and Navy instruction are in works due to revisions to “Common Rule”

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DFARS Clause 252.235-7004
Protection of Human Subjects

• The clause simply reinforces current regulations by adding procedures on how to apply the requirements within the acquisition framework.

• How this affects your contract-
  • Implementation of the clause restricts the award of any DoD funding until requirements are met.
  • Restricts the Contractor from expending funding on research involving human subjects until receiving notification from the HRPO that documents have been approved.

• Tasking and costs for human subject research should be clearly delineated and costed from other tasking as these tasks will be awarded as “options” once requirements are met.
IRB Documentation Requirements prior to the release of DoD funds

- **Grantee/Contractor is required to complete all five steps prior to beginning human studies**
  1. Have/obtain a registered IRB with an FWA
  2. Obtain Institution IRB approval
  3. Obtain approved Ethics and Human Subject Protection certificates for all investigators (e.g. CITI Training)
  4. Submit all assurances, approval letters, protocols, training certs and supporting documentation to NIWC with filled out NIWC Compliance verification form for approval by HRPO (submission to HRPO is through COR). For eIRBs, we need screenshots of IRB documentation. Whatever your IRB sees, NIWC HRPO needs to see.
  5. Once NIWC compliance form is approved AND your grant/contract/optional task is awarded, you can begin human studies.

Bottom Line: If it goes through your IRB, NIWC HRPO needs to see it including Serious Adverse Events (SAE) and unanticipated problems involving risk to subjects or others (UPIRTSO).

**Please note that amendments and/or renewals require the same process prior to proceeding.**

***Use of military and/or civil servants as subjects enlist additional requirements. Speak with COR if planning to use individuals in this category***

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<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Submission Date to NIWC PAC</td>
<td>Project Start Date</td>
</tr>
<tr>
<td>Primary Institution</td>
<td>Project Title</td>
</tr>
<tr>
<td>Technical POC (Contact Information)</td>
<td>Administrative POC (Contact Information)</td>
</tr>
<tr>
<td>IRB Assurance Number</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>IRB Risk Level Determination</td>
<td>ORO Navy Addendum</td>
</tr>
<tr>
<td>Will this Protocol Use ORO Personnel (e.g., Civilians of Military)</td>
<td>Will this Protocol Use Military Facilities?</td>
</tr>
<tr>
<td>Human Testing Institution (if not prime - 8a GR Contract)</td>
<td>Principal Investigator (Protocol)</td>
</tr>
<tr>
<td>IRB Protocol Title (if different from project title)</td>
<td>IRB Protocol Number</td>
</tr>
<tr>
<td>IRB Protocol Number</td>
<td>Initial Approval Date</td>
</tr>
<tr>
<td>Protocol Renewal and/or Amendment?</td>
<td>Approval Date</td>
</tr>
<tr>
<td>IRB Documentation</td>
<td>(Please check that documentation is provided as an attachment and provide information below)</td>
</tr>
<tr>
<td>IRB Protocol (Doc file name)</td>
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<tr>
<td>IRB Approval Letter (Doc file name)</td>
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<tr>
<td>IRB Consent Form (Doc file name)</td>
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<tr>
<td>PI Certification Training (Doc file name)</td>
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<tr>
<td>Certification Training All Key Personnel (Doc file name)</td>
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<tr>
<td>ORO Navy Addendum Approval Letter (Doc file name)</td>
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<tr>
<td>FWA Assurance (Doc file name)</td>
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<td>Review Date</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
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<tr>
<td>Signature Date</td>
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</tbody>
</table>
Considerations for HSR outside of the U.S with DoD funds

- Foreign IRBs reviewing DoD funded research will need an FWA
- A third party IRB with a FWA may be best option
• Obtain FWA through the Office of Human Research Protections (OHRP) website. You will need a registered Institutional Review Board (IRB) as part of the application process.
  http://www.hhs.gov/ohrp/assurances/assurances/file/index.html

• Complete Ethics and HSRP training training for all investigators on protocol
  • http://www.citiprogram.org use DON/ DON Extramural Performer
  • Institutional training may satisfy the requirements pending approval from DON HRPP
• Obtaining IRB required approvals from FDA
• Obtaining institutional agreements if one IRB relying on other and/or data sharing agreements.
SOW Tasking and Human Subject Research

• Identify subtasks that involve Human Subject Research and provide cost breakout in budget spreadsheet

• Group subtasks or otherwise identify as falling under each specific protocol. (If you anticipate multiple protocols for your effort)

• Ensure IRB approvals are in Milestone timelines for each protocol (allow 4 weeks for HRPO approval and award of task funding)
IACUC- Three step process. Grantee/Contractor is required to complete all four steps prior to beginning animal studies

1. Obtain Institution IACUC approval
2. Submit docs and Obtain ACURO IACUC approval
3. Submit all approvals, protocols, supporting documentation to NIWC with filled out NIWC Compliance verification form.
4. Receive signed NIWC compliance form back from NIWC.

Once you receive an approved NIWC compliance form back, you may proceed under protocol

** DARPA authorization for award prior to IACUC approval required.

Please note that amendments and/or renewals require the same 3 step process prior to proceeding.

Questions concerning animal use and review should be directed to the USAMRMC ACURO:

Phone: 301-619-6694
Email: acuro@amedd.army.mil
Mail: U.S. Army Medical Research and Materiel Command
      ATTN: MCMR-RPA
      504 Scott Street
      Fort Detrick, MD 21702-5012

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### NIWC PACIFIC IACUC COMPLIANCE DOCUMENTATION COVERSHEET

**Date Submitted to NIWC**

**This information pertains to PI**

**This information would pertain to PI on protocol (i.e. sub or prime)**

**PI required to resubmit documents to ACURO and NIWC when renew and/or amend**

**Date would be same as protocol expiration date**

**To be filled out by NIWC only**

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<th>This information pertains to PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date would be same as protocol expiration date</td>
<td>To be filled out by NIWC only</td>
</tr>
</tbody>
</table>

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**Note- once you get an “approved” form back investigator is free to proceed under protocol**

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STATEMENT OF WORK

1. INTRODUCTION
The Defense Advanced research Projects Agency (DARPA) Biological Technology Office (BTO) has identified a new thrust area to enable

2. SCOPE
In this effort, the grantee shall develop, fabricate, assemble and test a new set of software and hardware tools designed …
To accomplish the goals, the contractor…
The project will be divided into five periods. The first, a base period, shall be twelve months and culminate in a demonstration. The second, third, and fourth and fifth periods, each one year in length shall be options, and have technology demonstrations at the end of each period. Subsequent option shall only be exercised following successful completion of the preceding option.

3. APPLICABLE DOCUMENTS
(a) DARPA BAA
(b) University proposal titled

4. PROJECT WORK DESCRIPTION AND REQUIREMENTS
The grantee shall provide the facilities and services necessary to develop the technologies described in reference (b).

4.1 Task One
   4.2 Task Two
   4.3 Task Three

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Reporting/Deliverables that will be required

- Reports and distribution are listed in the CDRLS/DATA Matrix and attachment to the contract/grant.
- Reviews (Copy of presentation materials to be provided at time of meeting)
- Regular technical updates on a bi-weekly or monthly basis, depending on the scope of the effort
- Monthly report: Financial Status Report, Gantt update,
- Quarterly reports: 28 Feb, 31 May, 30 Aug and 30 Nov and include required data/models and progress on tasking- format to be provided
- Human and animal research regulatory documentation
- Program Plan including WBS when revised
- Data(including software) and Hardware Descriptions, source code, drawings- as Required
- Final Report

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