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## Controlled Unclassified Information Guide

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## FOREWORD

### 1. DESCRIPTION

Protean aims to develop medical countermeasures (MCMs) against chemical and biological (CB) agents by targeting historically inaccessible mechanisms to prevent injury and lethality. This will allow for more effective countermeasures, that completely resolve poisonings and reduce chronic effects of exposure; things that no current MCM can do.

### 2. AUTHORITY

CUI elements referenced in this guide are under the authority of Executive Order 13556, Controlled Unclassified Information, November 4, 2010 (as amended) and in accordance with DoDI 5200.48, "Controlled Unclassified Information," March 6, 2020.

### 3. Distribution:

#### **Distribution Statement A**

1. PURPOSE

a. The purpose of this CUI guide is to ensure the protection of Protean information IAW DoDI 5200.48. Protean information must be controlled and stored consistent with DFARS 252.204-7012 requirements as detailed in National Institute for Standards and Technology (NIST) 800-171.

b. This guide is not for classified national security information as defined in Executive Order 13526, but identifies specific elements of sensitive information that are unclassified but require additional protections.

2. APPLICABILITY AND SCOPE: This guide applies information, material and processes generated by Protean. This guide is the basis for identifying, protecting and marking of information and material designated as a type of controlled unclassified information (CUI) associated with Protean. This guide is used in conjunction with related guidance (security classification guides, DoD Policy, etc) associated with the overall effort of Protean. The scope of this guide is based on Protean as planned at the date of this guide and may change over the course of Protean.

3. OFFICE OF PRIMARY RESPONSIBILITY (OPR): The Office of Primary Responsibility is BTO\_Security@darpa.mil.

4. CONTROLLED UNCLASSIFIED INFORMATION (CUI) CHALLENGES: CUI Challenges are directed to the OPR. Information is protected in accordance with this guide until the challenge is resolved.

5. CUI Categories. The following CUI Categories are used to protect Protean:

<https://www.archives.gov/cui/registry/category-list>

a. Defense: Controlled Technical Information (CTI). Controlled Technical Information means technical information with military or space application that is subject to controls on the access, use, reproduction, modification, performance, display, release, disclosure, or dissemination. Controlled technical information is to be marked with one of the distribution statements B through F, in accordance with Department of Defense Instruction 5230.24, "Distribution Statements of Technical Documents." The term does not include information that is lawfully publicly available without restrictions. "Technical Information" means technical data or computer software, as those terms are defined in Defense Federal Acquisition Regulation Supplement clause 252.227-7013, "Rights in Technical Data - Noncommercial Items" (48 CFR 252.227-7013). Examples of technical information include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals,

technical reports, technical orders, catalog-item identifications, data sets, studies and analyses and related information, and computer software executable code and source code.

b. Export Controlled Research (EXPTR). Related to the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions 15 CFR 734.8(b).

c. Inventions (INVENT). An invention is any art or process (way of doing or making things), machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States, in which the federal government owns or may own a right, title, or interest.

d. Patent Application (APP). Application for patent filed under 35 U.S.C. 111(a) that includes all types of patent applications (i.e., utility, design, plant, and reissue) except provisional applications. The nonprovisional application establishes the filing date and initiates the examination process. A nonprovisional utility patent application must include a specification, including a claim or claims; drawings, when necessary; an oath or declaration; and the prescribed filing fee.

e. (U) General Proprietary Business Information (PROPIN): Material and information relating to, or associated with, a company's products, business, or activities, including but not limited to financial information; data or statements; trade secrets; product research and development; existing and future product designs and performance specifications.

6. EXPORT CONTROL RESTRICTED INFORMATION: Each performer is responsible for assessing their technology and ensuring compliance with all export control laws and regulations. This CUI guide does not relieve any program participant from export control requirements.

## 7. DISCLOSURE of CUI.

a. **Public Disclosure.** Public Disclosure of any PROTEAN information must follow the DISTAR process. Please contact the PROTEAN OPR and [Public\\_Release\\_Center@darpa.mil](mailto:Public_Release_Center@darpa.mil) for additional guidance.

b. **Freedom of Information Act (FOIA) Requests.** All FOIA request are directed to the DARPA FOIA Office.

c. **Foreign Disclosure.** CUI controlled by DARPA may be shared with foreign nationals if access to such information would accomplish a lawful government purpose and would not be detrimental to national security and approved by the Program Manager, and Program Security Officer or higher DoD Authority.

8. CUI PROTECTION REQUIREMENTS: PROTEAN CUI must be stored in accordance with DODI 5200.48. Processing of CUI is only authorized on systems compliant with DFARS 252.204-7012 as detailed in NIST 800-171.

9. UNAUTHORIZED DISCLOSURE

a. Personnel must immediately report all unauthorized disclosures or suspected and known security incidents, and suspicious activities involving CUI to the PROTEAN PSO and PSR at [BTO\\_Security@darpa.mil](mailto:BTO_Security@darpa.mil).

b. Data breaches of Defense Industrial Base (DIB) networks and systems involving PROTEAN CUI material must be reported IAW DFARS 252.204-7012 requirements. In addition, all breaches must be reported to the DARPA Project contracting officer and program security officer (PSO) upon discovery.

## 10. INFORMATION PROTECTION GUIDANCE CHARTS

These charts are provided to assist in identifying what types of information associated with the Protean effort may be sensitive, provide guidance on the relevant markings for this information to control dissemination, and provide guidance on when these dissemination controls no longer apply. If at any time there are questions regarding which category of information something falls under, or what dissemination controls apply, individuals should request guidance from Biological Technology Office (BTO).

<b>Element of Information</b>	<b>Index</b>	<b>Category</b>	<b>Reason</b>	<b>LDC or Distribution Statement</b>	<b>Remarks</b>
<p>Capability development for the characterization of novel mechanisms of action associated with a chem-impacted protein when utilizing UNCLASSIFIED <b>threat</b> agents</p> <p>(Includes: novel biophysical methods, structural biology data, computational and modeling approaches, dynamics trajectories, protein functional studies, and technical documentation.</p>	<p>Export Control</p> <p>Defense</p>	<p>Export Controlled Research (EXPT)</p>	<p>15 CFR 734.8(b) DFARS 252.204.7012 and DoDI 5230.24</p>	<p>DISTRO C</p>	<p>DARPA reserves the right to extend CUI protections if necessary.</p>
<p>Capability development for the characterization of novel mechanisms of action associated with a chem-impacted protein when utilizing threat agent <b>simulants or surrogates</b>.</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>	<p>UNCLASSIFIED</p>

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Demonstration of efficacy of novel MCM intervention design <i>in vivo</i> ; including technical documentation and potential publication.	Defense	Controlled Technical Information (CTI)	DFARS 252.204.7012 and DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Information required for the design and development of modeling and simulation (M&S) software and tools of UNCLASSIFIED threat agents.  Includes: methodology, theoretical and computational models, databases, and the computer codes and algorithms that are used to retrieve, compute, process, and/or present the results.	Proprietary Business Information; Defense; Export Control	PROPIN; CTI; EXPTR	DoDI 5200.48 DFARS 252.204-7012 DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Open source, M&S software, tools, and scientific literature in the public domain.	N/A	N/A	N/A	N/A	UNCLASSIFIED
Raw data generated during the conduct of research, development, and acquisition (RD&A) for defense when utilizing UNCLASSIFIED threat agents or threat agent simulants or surrogates.	N/A	N/A	N/A	N/A	UNCLASSIFIED
Test results showing mechanistic differences between physiological and dysfunctional proteins during a	Defense	Controlled Technical Information (CTI)	DFARS 252.204.7012 and DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.

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process of interest when utilizing UNCLASSIFIED threat agents. Includes test results of the protein target if engaged with medical countermeasures.					
Test results showing mechanistic differences between physiological and dysfunctional proteins during a process of interest when utilizing threat agent <b>simulants or surrogates</b> . Includes protein target if engaged with medical countermeasures.	N/A	N/A	N/A	N/A	UNCLASSIFIED
Identification of protein mechanism of action associated with restoration of function for chem-impacted protein model when developed utilizing UNCLASSIFIED threat agents.	Defense	Controlled Technical Information (CTI)	DFARS 252.204.7012 and DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Identification of protein mechanism of action associated with restoration of function for chem-impacted protein model when developed utilizing threat agent <b>simulants or surrogates</b> .	N/A	N/A	N/A	N/A	UNCLASSIFIED

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Intervention design and associated technical documentation for efficacy ( <i>in vitro</i> or <i>in vivo</i> ) and absorption, distribution, metabolism, and excretion ( <i>in vivo</i> ).	Defense	Controlled Technical Information (CTI)	DFARS 252.204.7012 and DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Test results of <i>in vitro</i> tests or intervention design <i>in vitro</i> results that reveal a new capability, product, or enhancement of a capability against threat agent simulants or surrogates.	N/A	N/A	N/A	N/A	UNCLASSIFIED
Product profile information of intervention designs when associated with an UNCLASSIFIED threat agent or threat agent <b>simulants or surrogates</b> . Includes, but not limited to, half-life, toxicity profile, absorption, distribution, metabolism, and excretion of molecules.	Export Control  Defense	Export Controlled Research (EXPTR)  Controlled Technical Information (CTI)	15 CFR 734.8(b)  DFARS 252.204.7012 and DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Product profile information of intervention designs when <b>unrelated</b> to a threat agent. Includes, but not limited to, half-life, toxicity profile, absorption, distribution, metabolism, and excretion of molecules.	N/A	N/A	N/A	N/A	UNCLASSIFIED

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Half maximal effective concentration (EC50) and lethal dose 50% (LD50) information associated with novel intervention design when associated with a UNCLASSIFIED threat agent.	Intelligence	OPSEC  Controlled Technical Information (CTI)	DoDI 5230.24,  DFARS 252.204.7012 FAR 2.101 and 3.104	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Half maximal effective concentration (EC50) and lethal dose 50% (LD50) information associated with novel intervention design when UNRELATED to CB defense.	N/A	N/A	N/A	N/A	UNCLASSIFIED
Programmatic or regulatory submission documents to the Food and Drug Administration that contain information about UNCLASSIFIED CB agents and their properties	Export Control  Defense	Export Controlled Research (EXPTR)  Controlled Technical Information (CTI)	15 CFR 734.8(b)  DFARS 252.204.7012 and DoDI 5230.24	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.
Programmatic or regulatory submission documents to the Food and Drug Administration that contain information unrelated to CB defense.	N/A	N/A	N/A	N/A	UNCLASSIFIED
Establishing a method or technique AND its required concentration <i>in vivo</i> to achieve desired levels of protection.	Export Control	Export Controlled Research (EXPT)	15 CFR 734.8(b)	DISTRO C	DARPA reserves the right to extend CUI protections if necessary.

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	Defense	Controlled Technical Information (CTI)	DFARS 252.204.7012 and DoDI 5230.24		
Non-public data controlled by the business or individual as proprietary	Proprietary Business Information	General Proprietary Business Information (PROPIN)	18 USC 1905 29 USC 664	Federal Employees and Contractors Only (FEDCON)	DARPA will protect all PROPIN as CUI. Performers are <b>NOT REQUIRED</b> to protect their PROPIN a CUI
Inventions and Patent applications	Patent applications Inventions	APP INVENT	35 USC 186 35 USC 187 35 USC 205 48 CFR 27.305-4 37 CFR 401.13(c)(1) 37 CFR 401.13(c)(3)-(5)	Federal Employees and Contractors Only (FEDCON)	DARPA will protect all patents applications and inventions information as CUI. Performers are <b>NOT REQUIRED</b> to protect these as CUI unless the information is protected elsewhere within the CUI Guide

**Definitions**

**Threat agent.** Any chemical compound listed as a Schedule 1 chemical weapon under the Chemical Weapons Convention (CWC) or listed on the Export Controlled List.

**Threat agent simulant or surrogate.** Any chemical compound that mimics the properties of a threat agent by its mechanism of action or its physiological effect. Simulant and surrogate compounds are used in place of extremely hazardous agents during RDT&E activities.