

MTEC Intellectual Property Guidance Document

INTRODUCTION

One of the key tenets in any successful research program is the ability to exploit the Intellectual Property derived from the research. This Intellectual Property Guidance (the “Guidance”) is designed to provide a framework whereby the Medical Technology Enterprise Consortium (“MTEC”) and the individual organizations signing the Consortium Member Agreement (“Members”) can exploit the IP created in and by the MTEC. This Plan covers the protection, access, licensing, and handling of costs and proceeds related to Intellectual Property developed or controlled by MTEC.

The goal of this Plan is provide Members appropriate access to IP rights so they can secure a valuable return on their MTEC membership, while also protecting IP, as appropriate, for their own competitive purposes. The hallmark of this plan, as reflected in the Other Transactions Agreement between MTEC and the Government, is balancing the interests of the Government, Consortium, and Consortium Members, while offering maximum flexibility between the parties to negotiate specific IP terms appropriate for a particular collaboration.

This Plan specifically addresses:

- Deployment rights for partners, with a portion of the revenue from deployment of project-generated IP directed to be applied to funding future research projects.
- All prospective Consortium Members have agreed in advance to contribute (by license or otherwise) Background Intellectual Property on projects where relevant and appropriate.

The IP provisions of the Bayh-Dole Act, while not mandatory when an Other Transaction Agreement is used to fund research and development projects, are a proven framework for promoting the deployment and public availability of federally funded research; and are thus the starting point for MTEC IP discussions. Additional considerations are presented here to further promote MTEC sustainability and minimum protections for government-sponsored projects. For clarity, this Plan is subject to the terms of any funding agreement, or applicable law or regulation.

DEFINITIONS

- 1.1 **Intellectual Property** or **IP** is defined as the legal rights associated with technical know-how, technical data, discoveries, materials, samples, software, software programs, documentation, reports, regulatory filings, any and all other copyrightable materials, any invention or discovery that is or may be patentable

or otherwise protectable under title 35 of the U.S. Code and any other intellectual property rights of any kind or nature whatsoever.

- 1.2 **Background Intellectual Property** or **Background IP** is defined as rights that are controlled, owned, developed or licensed by a Consortium Member prior to the date of an applicable MTEC research project agreement, or that is conceived and first actually reduced to practice by such Consortium Member during the term of such MTEC research project agreement, but not in the course of the performance of such Consortium Member's activities thereunder such that it falls within the definition of **Consortium Developed Intellectual Property**.
- 1.3 **Consortium Developed Intellectual Property** or **CDIP** is defined, individually and collectively, as all IP that is conceived or first actually reduced to practice solely or jointly by any Member(s) of the Consortium as a part of and during the performance of an MTEC research project agreement funded in whole or in part by the Government or other third party.
- 1.4 **"Net Revenue"** is defined as and incorporates both "Net Licensing Revenue" and "Net Product Revenue" as set forth below.
 - 1.4.1 "Net Licensing Revenue" means all royalties, fees and other payments received by a Member in connection with any license of the Consortium Developed Intellectual Property, including without limitation, royalty payments, minimum annual royalty payments, upfront licensing fees, option fees, milestone fees, change in control fees or maintenance fees, but excluding reimbursement of patent application, prosecution and maintenance fees, any amounts payable to individual inventors pursuant to the Member's written policies, and internal administrative chargebacks such as for technology transfer or legal activities in accordance with the Member's written policies.
 - 1.4.2 "Net Product Revenue" means any consideration actually received by a Member from a third party in exchange for the development, manufacture, sale, license, use or provision of any process, method, system, material, composition, item compound, device or embodiment, product or part thereof which utilizes, comprises or is encompassed by the Consortium-Developed Intellectual Property (net of any tax or similar withholding obligations imposed by any tax or other government authority(ies)) less (a) the cost of goods

sold (meaning the actual unit costs of manufacturing and packaging the product, including direct materials costs, third party license costs, direct labor costs and overhead directly attributable to the manufacture of product); (b) shipping and insurance charges; (c) actual rebates, credits or refunds for returned or defective goods; (d) rebates, credits and chargeback payments actually granted in accordance with applicable law and standard industry practices; (e) any import or export duties, tariffs or similar charges incurred with respect to the import or export of covered products; in all cases as calculated in accordance with GAAP.

- 1.4.3 For clarification, “Net Licensing Revenue” and “Net Product Revenue” are not intended to be duplicative and a Member should pay royalties on revenue only once. A university or research organization would typically only be involved in licensing the intellectual property to a third party for commercialization and would therefore pay a royalty only on Licensing Revenue. However, a Member that is a commercializing entity may receive both Licensing Revenue and Product Revenue. For example, if the lead organization receiving funding is a commercial entity (“Company Member”), such Company Member may manufacture and sell Product directly in a territory, such as the U.S., and would therefore receive Product Revenue from such activities. Such Company Member may also license the intellectual property to a non-affiliated third party for commercialization in another territory, such as the EU, and would receive Licensing Revenue from such licensing activities. In this case, Company Member would pay royalties on both Net Product Revenue and Net Licensing Revenue.

GOVERNMENT DATA AND PATENT RIGHTS

It is understood that the United States Government (through any of its agencies or otherwise) may provide use of its facilities or equipment and / or may provide funds for medical research. Any and all rights and obligations of the Consortium Members to any CDIP resulting from use of any United States Government’s facilities, equipment or funds are subject to the terms and conditions of the MTEC Other Transactions Agreement Number (OTA) W81XWH-15-9-0001. Consortium Members will be required to execute MTEC Base Agreements which will flow down the pertinent terms, including the IP terms, from the OTA. All

OTA project funding will be issued by the MTEC Consortium Manager to the Consortium Member through Research Project Awards under that Consortium Member's MTEC Base Agreement. Base Agreements will be available to prospective Consortium Members upon request. Please see Appendix A for additional details regarding OTA terms. The terms of the OTA may be subject to change. Members will be notified of any such changes. Table 1 provides an overview of the allocations of rights based on the category of data as defined in Article 9 of the OTA (Appendix A).

Note: This table, as with the rest of this Plan, are for guidance only, and subject to the terms of the OTA.

Table 1. Government Data Rights Summary (see Appendix A for additional details)

Category	Description	Allocation of Rights under OTA	Allocation of Rights under third party funding
Category A Data	Data developed and paid for by totally private funds	Government has “limited” or “restricted” rights	Sponsor dependent
Category B Data	Data developed previously or with mixed funding	Rights negotiated under a prior agreement. Government shall normally have immediate unlimited or Government purpose license rights upon project completion	Sponsor dependent
Category C Data	Data developed exclusively with Government funds through MTEC	Government has unlimited rights except as provided in separate agreement	Sponsor dependent
Category D Data	Specifically- negotiated data rights by agreement of the parties. Sufficiently flexible to meet the needs of the parties.	A specifically- negotiated data rights agreement should be included in a research project award.	Sponsor dependent

Patent Rights for work funded by this Agreement shall be substantially the same as FAR 52.227-11 (“Patent Rights – Ownership by the Contractor {May 2014}”), <https://www.acquisition.gov/far/>, which is hereby incorporated by reference with the following modifications.

With respect to Patent Rights, the Government acknowledges and agrees that its rights will depend upon its financial contributions.

- If the Government contributes between 0-49% of the Research Project Award costs, the Government shall obtain a nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced for or on its behalf, for government purposes, the subject invention throughout the world.
- If the Government contributes between 50%-100% of the Research Project Award costs, the Government shall obtain the same license rights with the ability to transfer the license for commercial purposes.

Although this agreement affords the Government certain rights for inventions made by Members, it is in the Governments best interest to see technologies move to market. As such, differing patent rights may be negotiated among the Members of each individual Research Project Award on a case-by-case basis.

In addition, the following modification to FAR 52.227-11, Subclause (b) "Contractor's rights" is made:

Government Employee Inventions. The Parties agree that the U.S. Government shall have the initial option to retain title to each Subject Invention made only by its employees. The Government shall promptly notify the Consortium and Consortium Members upon making this election, and in the event that the Government informs the Consortium and Consortium Members that it elects to retain title to such Subject Invention, the Government agrees to timely file patent applications thereon at its own expense. The Government agrees to enter into negotiations in good faith with the Consortium and Consortium Members for a license to Consortium or Consortium Members of the Government's interests to the invention within specified fields of use, at reasonable rate, terms, and conditions. Any such license agreement shall be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. The Government may release the rights provided for by this paragraph to its employee inventors subject to any license to the Consortium and Consortium Members as described above.

Joint Employee Inventions. Title to Subject Inventions made jointly by employees of the Government and Consortium or Consortium Members shall be held jointly by the Government and Consortium or Consortium Members. Consortium or Consortium Members shall have the initial option to file patent applications on joint Subject Inventions at its own expense.

In the event that the Consortium or Consortium Members decline to file or complete prosecution of such patent application, Consortium or Consortium Members waive its co-ownership interest and agree to assign its title to such joint Subject Inventions to the Government in exchange for a non-exclusive, irrevocably paid-up license to practice such Subject Invention throughout the world.

In the event that Consortium or Consortium Members elect to file and complete prosecution of such patent applications, the Government agrees to enter into negotiations in good faith with Consortium or Consortium Members for a license to Consortium or Consortium Members of the Government's interests to the invention within specified fields of use, at reasonable rate, terms, and conditions. Any such license agreement shall be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

Consortium or Consortium Members shall notify the Government in writing of its interest in obtaining such exclusive license rights within thirty (30) days of Subject Invention filing.

INTELLECTUAL PROPERTY RIGHTS BETWEEN MEMBERS

- 2.1 **Background Intellectual Property.** Each Member shall retain all rights to its Background Intellectual Property subject only to the IP sharing or access summarized in this Plan; the decision to make available any such Background Intellectual Property for use in a Member's research project, or subsequently for commercial purposes, shall be at the sole discretion of each Member. MTEC, as part of its project solicitation, will require proposers to identify all Background IP required for performance of a research project. In addition, project participants will be required to provide any updates to Background IP needed during project execution, if necessary. Each Background IP owner will be required to grant a royalty-free, worldwide, non-exclusive research/educational use license to other parties solely for use in that research project.
- 2.1.1 In the event that one Member may require use of another Member's Background Intellectual Property that has been disclosed by a Member as part of an MTEC research project in order to successfully deploy any CDIP, then the Members agree to discuss potential licensing terms and conditions in a separate legally binding agreement between the Members, separate from this Plan. Member(s) are not required to license any such originating Member's Background Intellectual Property.
- 2.2 **Consortium Developed Intellectual Property.** All CDIP shall be owned by the respective inventing or creating Members, subject to any Government rights and/or any pre-existing rights of any third party and subject to the following conditions:
- 2.2.1 If a Member solely or jointly creates CDIP, the Member must disclose the creation of such CDIP to its technology transfer office, licensing office or other similar department ("Licensing/ Tech Transfer Office"). A non-enabling summary of the CDIP disclosed to the Member's Licensing/Tech Transfer Office shall be sent to the MTEC Chief Operating Officer as soon as is practical so that MTEC can maintain a list of CDIP. Members owning CDIP shall grant upon request to MTEC and Members-In-Good-Standing at the time of creation a limited, non-exclusive, worldwide, royalty-free license to use the CDIP for MTEC's and any such Member's internal procedures, research or development purposes (but not to make, use, or sell products or external processes for commercial purposes, with the exception of licenses granted pursuant to Section 3). Such licenses shall be granted to

interested Members upon request in a separate, legally binding, mutually agreeable license agreement between the Members. Payment of patent expenses may be required of parties granted non-exclusive, royalty-free commercial licenses by universities and other not-for-profit institutions. Such licenses for Members shall be without the right to grant sublicenses to third parties, except for any Member-designated agents, contractors and non-employee students (“Permitted Third Parties”) performing work for the benefit of such Member. Under these circumstances the Member is responsible for having any and all appropriate written agreements with such Permitted Third Parties to enable Member’s compliance with this Plan and is responsible for such parties’ use of the CDIP in the same manner Member is responsible for its own use of such CDIP (e.g., violation of the license parameters set forth in this section by a Member’s Permitted Third Parties shall be considered a breach of this Plan by such Member).

2.2.2 MTEC will encourage Members, both during research project execution and upon project completion, to seek patent protection as soon as is reasonably possible following disclosure of all CDIP to MTEC. Protection of a Member’s solely-developed CDIP shall be done at Member’s own expense and through use of their respective Licensing/Tech Transfer Office. With respect to jointly developed CDIP, the relevant Members will negotiate a separate legally-binding agreement encompassing those terms and conditions to be used to govern the manner in which jointly developed CDIP will be owned, administered, protected, and licensed. The MTEC Director of Commercialization will be notified in writing in a timely manner of the existence of these agreements between Members, and MTEC shall maintain pertinent information in its invention disclosure database. In the event that a single Member for solely developed CDIP, or all Members with an ownership right for jointly developed CDIP, choose not to seek legal protection and thereby elect not to file a patent application on any CDIP, then Member(s) will notify the MTEC Director of Commercialization in writing of its intent and must report to MTEC at the time of this notification any pending publication, presentation, disclosure to third party, public use, or offer for sale, or any other activity that would create a statutory bar to patent protection. Member(s) must refrain from creating statutory bars to patent protection in cases where MTEC or the Government may want to seek patent protection at its own expense in exchange for assignment of title to the invention. MTEC or the Government may obtain such protection at its own expense where Member(s) choose not to seek legal

protection. Ownership of CDIP shall remain with the originating Member(s) absent any agreement to transfer title.

- 2.2.3 It is anticipated that one of the outcomes of an active IP licensing and deployment plan is the generation of royalty income by a respective Member. It is acknowledged that Members from industry and academia will manage the disposition and reporting requirements of all royalties received in accordance with government laws and regulations and their institution's existing policies, through their Licensing/Tech Transfer Office. To the extent they may legally do so, Members owning CDIP shall grant MTEC and Members-In-Good-Standing a limited, non-exclusive, worldwide, royalty-bearing license to use the CDIP for commercial purposes. Members-In-Good-Standing shall be granted such licenses at a fair market value royalty rate. Such licenses shall be granted to interested Members upon request in a separate, legally binding, mutually agreeable agreement between the Members. Such licenses for Members shall be without the right to grant sublicenses to third parties, except for any Member-designated agents, contractors, treaty partners, and non-employee students performing work for the benefit of such Member, provided, however, the Member is responsible for having any and all appropriate written agreements with such parties to enable Member's compliance with this Agreement and is responsible for such parties' use of the CDIP in the same manner Member is responsible for its own use of such CDIP (e.g., violation of the license parameters set forth in this section by a Member's contractor shall be considered a breach of this Agreement by Member). In addition, sublicensing shall be permitted to the licensee's end users.
- 2.2.4 Notwithstanding anything to the contrary in this Agreement, certain laws, regulations and/or policies may prevent and/or limit certain Members' ability to offer royalty-bearing licenses to CDIP that has previously been licensed by such Members on a royalty-free basis. Therefore, the ability to charge royalties to Members and/or third parties is subject to the granting Member's ability to do so in light of then-existing contractual obligations, legal and regulatory requirements, and policies of the granting Member.
- 2.2.5 Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the research project award recipient resulting from the licensing/commercialization of technology, capped at 200% of the government funding provided. In lieu

of providing royalty payments, Members may elect to pay an additional project award assessment above the standard assessment described in Section 3.4 of the Consortium Member Agreement. At the time of research project award, an MTEC member will either sign a Royalty Agreement or agree to pay an additional project award assessment, per Section 11.17 of the Consortium Member Agreement. These terms are intended to provide a modest return to MTEC for successful translation of technologies to licensing and commercialization stages, as well as to support the MTEC goal of becoming financially self-sustainable. MTEC projects funded by private sponsors may be subject to separately-negotiated royalty terms.

LICENSING AND SUBLICENSING OF MTEC CONTROLLED IP

- 3.1 Central to MTEC’s strategy to stimulate research in the medical industries is to partner with technology innovators who have “game changing” Background Intellectual Property and are seeking commercial applications of their IP in the MTEC technology areas.
- 3.2 By partnering with MTEC, these innovators will have the access to companies from MTEC to showcase their Background Intellectual Property technology.
- 3.3 MTEC will seek to negotiate license rights with these innovators containing the following terms:
 - 3.3.1 License will allow MTEC to sublicense innovator’s Background Intellectual Property to other Members for limited, non-exclusive internal use or internal R&D rights for MTEC research projects.
 - 3.3.2 MTEC will be able to sublicense internal use or internal R&D rights at no charge as cost share under the applicable Other Transactions Agreement.
 - 3.3.3 MTEC and innovator will negotiate a nonexclusive/exclusive, royalty-bearing license for all resulting commercial applications of innovator’s Background Intellectual Property in the MTEC target industries.
- 3.4 This technology transfer and deployment strategy supports the goal of this Plan, which is to ensure that MTEC has sufficient access to IP to help the Consortium survive, sustain and grow, and that Members have appropriate access to use rights to develop products for a competitive advantage.

Appendix A

MTEC OTA Flowdown Terms and Conditions Regarding Intellectual Property

ARTICLE 9. RIGHTS IN TECHNICAL DATA, COMPUTER SOFTWARE, AND COPYRIGHTS

9.1. General. This Rights in Technical Data and Computer Software Article is specifically tailored for this Agreement to address respective rights of the Government and the Consortium on behalf of Research Project Awardees to such Data and Computer Software as is owned, developed, to be developed or used by an actual or prospective Research Project Awardee (1) as identified in a Research Project Proposal submitted to the Government through the CM in response to a Request for Proposals, and (2) when such proposal is selected by the Government for funded performance and the Research Project Award is issued by the CM to that Research Project Awardee for performance of such research and development initiative.

9.2. Definitions.

- 9.2.1. "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).
- 9.2.2. "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this Agreement) is sold or offered for sale, lease or license to the general public.
- 9.2.3. "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.
- 9.2.4. "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.
- 9.2.5. "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.
- 9.2.6. "Research Project Awardee Data" as used in this Article means Data developed or made by and in the course of performing identified assigned tasks by any Research Project Awardee.
- 9.2.7. "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

- 9.2.8. “Form, fit and function data” means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.
- 9.2.9. “Government purpose rights” means the rights to use, modify, duplicate or disclose the “Data” licensed with such rights under this Agreement within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than five (5) years and during such time the Research Project Awardee developing or providing such Data to the Government with Government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another initiative issued to that Research Project Awardee under this Agreement during this five (5) year period, the period of Government purpose rights shall be extended an additional five (5) years starting with the date of completion of performance of the additional initiative.
- 9.2.10. “Limited rights” as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).
- 9.2.11. “Regulatory Application” as used in this Article is an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted or planned for submission to the U.S. Food and Drug Administration (FDA) related to the research under a Research Project Award.”
- 9.2.12. “Restricted rights” as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).
- 9.2.13. “Small Business Innovated Research (SBIR) data rights” as used in this Article is as defined in DFARS 252.227-7018(a)(19).
- 9.2.14. “Specially Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the CM on behalf of the Research Project Awardee whose proposal is selected by the Government under a call for proposals issued under the Agreement.
- 9.2.15. “Technical data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer

software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

- 9.2.16. “Unlimited rights” means the rights to use, modify, duplicate, release, or disclose Data, in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

9.3. Data Categories

- 9.3.1. Category A is the Data developed and paid for totally by private funds, or the Research Project Awardee (or its subawardee's) IR&D funds and it is Data to which the Government has “Limited” or “Restricted” rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the Research Project Awardee for an initiative under this Agreement which was not developed in the performance of work under that initiative, and for which the Government has “Limited” or “Restricted” rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the initiative by any of the Research Project Awardees. Such Data shall be marked “Category A” and any rights to be provided to the Government for such Data under a specific initiative shall be as identified in the proposal submitted to the Government and included into the Project Approval Letter, pOTA task order, and CM issued Agreements.

- 9.3.2. Category B is any Data developed previously or under this Agreement with mixed funding, i.e. development was accomplished partially with Government funding under this Agreement. Any Data developed outside of the Research Project Award whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subaward shall have the rights negotiated under such prior agreement, contract or subaward; the Government shall get no additional rights in such Data.

- 9.3.3. Category C is any Data developed exclusively with Government funds under this Agreement. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

(a) the Government will have Unlimited Rights in Data developed exclusively with Government funds under an initiative funded by the Government under this Agreement that is:

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the Agreement that relates to the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (including detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Research Project Awardee or Subawardee without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(ix) Data furnished to the Government, under this or any other Government contract or subaward thereunder, with—

(A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or

(B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has/have expired.

(x) Data included in any Regulatory Application, as defined in Article 9.2.11, or comprising a component thereof”

(b) However, any Data developed outside of this Agreement whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subaward shall have the rights negotiated under such prior agreement, contract or subaward; the Government shall get no additional rights in such Data.

(c) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this Agreement,

and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

9.3.4. Category D is any Data developed under any specifically-negotiated data rights agreement consistent with paragraph 9.9 of this article. Any data developed under a specifically-negotiated data rights agreement will have the character and rights specified therein and may be flexible to meet the needs of the parties. Any such specifically-negotiated data rights agreement will be included in the associated Research Project Award. Specifically-negotiated data rights are the exception to the standard Categories A, B and C data described in the forgoing paragraphs. Absence of specifically-negotiated data rights in the Research Project Award will render the data rights allocated consistent with the forgoing paragraphs.

9.3.5. The Government can only order such Data as is developed under the Research Project Award where the order request is made within one (1) year following Research Project Award completion. In the event the Government orders such Data, it shall pay CM or Research Project Awardee the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

9.3.6. The parties to this Agreement understand and agree that the CM shall have its Research Project Awardees stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

9.4. Allocation of Principal Rights

9.4.1. The Government shall have “limited” or “restricted” rights to Category A Data.

9.4.2. The Government shall normally have immediate Unlimited or Government Purpose License Rights to Category B or C Data upon initiative or Agreement completion (whichever is earlier), except that

(a) for Article 9 B.3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(b) for Article 9 B.3 9(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

9.4.3. Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific initiative award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government’s rights to use,

modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

- 9.4.4. Each proposal submitted by the CM on behalf of an individual or team of Research Project Awardees in response to a Government call for proposals under this Agreement shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.
- 9.4.5. Following issuance of an Project Approval Letter, pOTA task order, and subsequent CM issuance of the Research Project Award, the CM on behalf of the Research Project Awardee shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

9.5. Marking of Data

- 9.5.1. Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:
- Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the Consortium, Agreement No. W81XWH-15-9-0001, Proposal Title with [insert name of company] No. _____.
- 9.5.2. It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.
- 9.5.3. In the event commercial computer software and Data is licensed under a commercial computer software license under this pOTA, a Special License rights marking legend shall be used as agreed to by the parties.
- 9.5.4. The Government shall have unlimited rights in all unmarked Data. In the event that an Research Project Awardee learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CM on behalf of the Research Project Awardee will have the opportunity to cure such omission going forward by providing written notice to the AO within three (3) months of the erroneous release.

9.6. Copyright

- 9.6.1. The CM on behalf of the Research Project Awardees reserves the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual Research Project Awardee(s). The Research Project Awardees hereby grant to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for Governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.
- 9.6.2. In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.
- 9.6.3. Except that copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.
- 9.6.4. The Research Project Awardees are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.
- 9.6.5. The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

9.7. Data First Produced by the Government

- 9.7.1. As to Data first produced by the Government in carrying out the Government's responsibilities under this Agreement and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CM on behalf of any Research Project Awardee, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CM and any Research Project Awardee to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CM or Research Project Awardee, including its respective employees or subawards of any tier,

(under suitable protective conditions) by or on behalf of the Government for Government purposes only.

9.8. Prior Technology

- 9.8.1. Government Prior Technology: In the event it is necessary for the Government to furnish the CM or any Research Project Awardee, including their respective employees or their subawards of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by the CM, Research Project Awardees, or subawards of any tier and their respective employees to whom such Data is provided for use under the Agreement. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.
- 9.8.2. CM and Research Project Awardee: In the event it is necessary for the CM or Research Project Awardee to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CM or Research Project Awardee shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CM on behalf of itself or Research Project Awardees.
- 9.8.3. Oral and Visual Information: If information which the CM, Research Project Awardees, or their subawards of any tier and their respective employees considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government within ten (10) calendar days after such oral or visual disclosure, or the Government shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

9.8.4. Disclaimer of Liability: Notwithstanding the above, the Government shall not be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article 8 entitled "Proprietary Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or is generated by the Government independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the CM or Research Project Awardee has furnished, or is required to furnish to the Government without restriction on disclosure and use. Information designated as Confidential or "Proprietary Information" shall not be disclosed, copied, reproduced, or otherwise made available in any form whatsoever to any other person, firm, corporation, partnership, association, or other entity without the consent of the Collaborator except as such information may be subject to disclosure under the Freedom of Information Act (5 U.S.C. 552).

9.8.5. Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

9.9. Negotiating Other Rights. Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual initiative on a case-by-case basis.

9.10. Flow Down. The Consortium through its CM shall include this Article, suitably modified, to identify all parties, in all Research Project Awards or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The Government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

9.11. Survival Rights. Provisions of this Article shall survive termination of this Agreement under Article II. Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Research Project Award on a case-by-case basis.

Article 10. INVENTIONS

10.1. Patent Rights. Patent Rights for work funded by this Agreement shall be substantially the same as FAR 52.227-11 ("Patent Rights – Ownership by the Contractor {May 2014}"), <https://www.acquisition.gov/far/>, which is hereby Attachment # 1 pOTA, Page 35 incorporated by reference with the following modifications. With respect to Patent Rights,

the Government acknowledges and agrees that its rights will depend upon its financial contributions. If the Government contributes between 0-49% of the Research Project Award costs, the Government shall obtain a nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced for or on its behalf, for government purposes, the subject invention throughout the world. If the Government contributes between 50%-100% of the Research Project Award costs, the Government shall obtain the same license rights with the ability to transfer the license for commercial purposes. In addition, the following modification to FAR 52.227-11, Subclause (b) "Contractor's rights" is made:

10.2. Government Employee Inventions. The Parties agree that the U.S. Government shall have the initial option to retain title to each Subject Invention made only by its employees. The Government shall promptly notify the Consortium and Consortium Members upon making this election, and in the event that the Government informs the Consortium and Consortium Members that it elects to retain title to such Subject Invention, the Government agrees to timely file patent applications thereon at its own expense. The Government agrees to enter into negotiations in good faith with the Consortium and Consortium Members for a license to Consortium or Consortium Members of the Government's interests to the invention within specified fields of use, at reasonable rate, terms, and conditions. Any such license agreement shall be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. The Government may release the rights provided for by this paragraph to its employee inventors subject to any license to the Consortium and Consortium Members as described above.

10.3. Joint Employee Inventions. Title to Subject Inventions made jointly by employees of the Government and Consortium or Consortium Members shall be held jointly by the Government and Consortium or Consortium Members. Consortium or Consortium Members shall have the initial option to file patent applications on joint Subject Inventions at its own expense.

10.3.1. In the event that the Consortium or Consortium Members decline to file or complete prosecution of such patent application, Consortium or Consortium Members waive its co-ownership interest and agree to assign its title to such joint Subject Inventions to the Government in exchange for a non-exclusive, irrevocably paid-up license to practice such Subject Invention throughout the world.

10.3.2. In the event that Consortium or Consortium Members elect to file and complete prosecution of such patent applications, the Government agrees to enter into negotiations in good faith with Consortium or Consortium Members for a license to Consortium or Consortium Members of the Government's interests to the invention within specified fields of use, at reasonable rate, terms, and conditions. Any such license agreement shall be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

10.3.3. Government reserves the right to ensure that any license it grants to the Consortium or Consortium Members is consistent with the Government's international treaty and agreement obligations.

10.3.4. Consortium or Consortium Members shall notify the Government in writing of its interest in obtaining such exclusive license rights within thirty (30) days of Subject Invention filing.

10.4. Patent Reports. The Consortium or Consortium Members shall file Invention (Patent) Reports as of the close of the performance year and at the end of each project award for this Agreement or more frequently if a statutory bar will occur before the next annual or final project report. Annual reports are due sixty (60) calendar days after the expiration of the final performance period. The recipient shall use DD Form 882, Report of Inventions and Subawards (or forms appropriate to non DoD agencies), to file an invention report. Such reports are required whether or not a Subject Invention was made. The patent recipient Consortium Member(s) shall submit the original and one copy to the AO, and one copy to the technology scientist or engineer.

10.5. Authorization and Consent. The Government authorizes and consents under 28 U.S.C. 1498 to all use and manufacture of any invention described in and covered by a United States patent in the performance of this Agreement or any subaward at any tier.

10.6. Final Payment. Final payment cannot be made nor can the Agreement be closed-out until the patent recipient, Consortium or Consortium Members deliver to the Government all disclosures of Subject Inventions required by this Agreement, an acceptable final report pursuant to the article entitled "Reports," and all confirmatory instruments.

10.7. Cooperation. The Government and the Consortium and/or Consortium Members shall keep the other informed as to the status of joint patent matters. The Government and the Consortium and/or Consortium Members shall each reasonably cooperate with and assist the other at its own expense in connection with such activities, at the other Party's request during the term of this Agreement.

10.8. Flow Down. The Consortium through its CM shall include this Article, suitably modified, to identify all parties, in all Research Project Awards or subawards. This Article shall, in turn, be included in all sub-tier subawards or other forms of lower tier agreements, regardless of tier. The government will be a third party in interest for purposes of this Article in any agreement where flow-down of rights and obligations is required.

10.9. Differing Patent Rights. Notwithstanding Paragraphs 10.1 through 10.5 above, differing patent rights may be negotiated among the Parties to each individual Research Project Award on a case-by-case basis.