

Government Contracts Flowdowns for United States Government (“Government”)
Funded Orders

1. **SUPPLEMENTAL NATURE OF PROVISIONS.** The terms and conditions included in these General Flowdowns are in addition to, and not in lieu of, any other terms contained in or incorporated into the Purchase Order or other agreement between the parties (the “Agreement”). In the event of a conflict between these provisions and the Agreement provisions, these provisions shall control. The term “Order” is used herein to refer to Purchase Orders, whether independently issued or issued under an Agreement. As used herein, the terms, “Fujifilm” and “Supplier” shall mean the parties so identified in the applicable Order. If you have questions as to which of these Flowdowns are applicable to your Order, it is your responsible to inquire with Fujifilm.

2. **TERMS AND CONDITIONS APPLICABLE TO ALL GOVERNMENT FUNDED ORDERS**

2.1. Defense Priority Rating. If so identified, this Order is a “rated order” certified for national defense use, and Supplier shall follow all the requirements of the Defense Priorities and Allocation System Regulation (15 C.F.R. Part 700). Additionally, Supplier acknowledges that subsequent to placing the Order, the US Government may require Fujifilm to modify the Order to a rated order and upon notice, this Order will become a “rated order” and Supplier shall follow all requirements of the Defense Priorities and Allocation System Regulations (15 C.F.R., Part 700).

2.2. HHS Priority Rating. If so identified, this Order is a “rated order” certified for national defense use, and Supplier shall follow all the all the provisions of the Health Resources Priorities and Allocations System regulation at 45 CFR part 101. Additionally, Supplier acknowledges that subsequent to placing the Order, the US Government may require Fujifilm to modify the Order to a rated order and upon notice, this Order will become a “rated order” and Supplier shall follow all requirements of the Health Resources Priorities and Allocations System (45 CFR part 101).

2.3. Export Control.

Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR):

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act and that such data require an approval,

authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- this document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401 et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

Flow down. Subcontractor shall include this Section 2.2, suitably modified, to identify all Parties, in all lower tier agreements.

3. STATUTORY AND REGULATORY FLOWDOWNS

The requirements of the FAR and other agency clauses and federal statutes cited throughout this Order and the clauses cited below are incorporated herein by reference with full force and effect, as if set forth in full text. If no effective date is provided, the effective version of each clause shall be the same version as that which appears in Fujifilm's prime contract with the federal government or higher-tier subcontract under which this Order is a subcontract. If any of the clauses are not applicable by their terms they shall be self-deleting.

In all clauses listed herein, terms shall be revised to suitably identify the party to establish Supplier's obligations to Fujifilm and to the Government, and to enable Fujifilm to meet its obligations under its prime contract or higher-tier subcontract, as applicable.

Without limiting the generality of the foregoing, the term, "Contracting Officer" means "Fujifilm's Authorized Representative," "Contractor" shall mean "Supplier," "Subcontractor" shall mean "Supplier's Subcontractor" under this Order, "Contract" means the Order, and "Government" means "Fujifilm." However, notwithstanding the foregoing, the words "Government" and "Contracting Officer" do not change: (1) when a right, act, authorization or obligation can be granted or performed only by the Government or the prime contract Contracting Officer or duly authorized representative or (2) when title to property is to be transferred directly to the Government. Supplier shall incorporate into each lower tier contract issued in support of this Order these General Flowdowns, as applicable, in accordance with the respective flowdown requirements specified therein.

3.1 Federal Acquisition Regulations

3.2 DFARS

FAR Reference	Clause Name
52.203-6 (Alt 1)	Restrictions on Subcontractor Sales to the Government
52.203-7	Anti-Kickback Procedures
52.212-4(c)	Changes
52.212-4 (I)	Contract Terms and Conditions – Commercial Items (Termination for the Governments’ Convenience)
52.222-37	Employment Records of Special Veterans (if Subcontract exceeds \$150k)
52.222-39	Notification of Employee Rights
52.222-54	Employment Eligibility Verification
52.225-13	Restrictions on Certain Foreign Purchases
52.226-6	Promoting Excess Food donation to Nonprofit Org
52.244-6	Subcontracts for Commercial Items (each of the clauses listed at FAR 52.244-6 is incorporated by reference into this Agreement)
Clause Reference	Clause Name
252.203-7002	Requirement to Inform Employees of Whistleblower Rights
252.204-7000	Disclosure of Information
252.225-7048	Export Control Items
252.227-7015	Technical Data – Commercial Items
252.227-7016	Rights in Bid or Proposal Information
252.227-7025	Limitations on the Use or Disclosure of Government Furnished Information Marked with Restrictive Legends
252.244-7000	Subcontracts for Commercial Items

4. EQUAL OPPORTUNITY; NONDISCRIMINATION

This clause 4 shall apply to Government funded contracts, except to the extent such application is prohibited by law, court order or executive order.

41 CFR 60-1.4(a), 60-300.5(a) and 60-741.5(a). Fujifilm and Supplier shall abide by the requirements of 41 CFR §§ 60-1.4(a), 60-300.5(a) and 60-741.5(a), which are incorporated herein by reference, as applicable. These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, sexual orientation, gender identity or national origin. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ individuals without regard to race, color, religion, sex, sexual orientation, gender identity, or national origin, and to employ and advance in employment qualified individuals with disabilities and protected veterans.

41 CFR 61-300.10; 29 CFR Part 471, Appendix A to Subpart A. If applicable in accordance with its terms, Fujifilm and Supplier shall also abide by the requirements of 41 CFR 61-300.10 regarding veterans' employment reports and 29 CFR Part 471, Appendix A to Subpart A regarding posting a notice of employee rights.

5. ADDITIONAL CONTRACTUAL FLOWDOWNS APPLICABLE TO SERVICES AND GOODS PROVIDED TO FUJIFILM DIOSYTNH AS FUNDED BY ANY MCDC BASE AGREEMENT. In addition to the clauses set forth in Sections 2 and 3 herein, the following shall apply to any Goods or Services funded by any MCDC Base Agreement.

5.1. Definitions. The following terms shall have the following meanings in this Section 5, 6 and 7:

“Consortium Management Firm (CMF)” means the organization acting on behalf of the MCDC to execute and administer the efforts under the OTA for this program, as defined in the specific agreement entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

“MCDC” means the Medical CBRN Defense Consortium

“Project Agreement (PA)” means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms, and conditions for the MCDC member entity's performance and payment under the Government funded project. PAs shall comply with all provisions contained within the OTA and any other supporting documents

referenced therein. The PA is initiated by the CMF based on the Technical Direction Letter (TDL) or Project Order sent by the Government to the CMF.

5.2 Confidential Information

(a) Definitions

- (i) “Disclosing Party” means the prime contractor, Fujifilm, Supplier or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
- (ii) “Receiving Party” means the prime contractor, Fujifilm, Supplier, or the Government who receives Confidential Information disclosed by a Disclosing Party.
- (iii) “Confidential Information” means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret, if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information, and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. “Confidential Information” includes any information and materials considered a Trade Secret by the prime contractor. “Trade Secret” means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes,

whether tangible or intangible, regardless of how it is stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if

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- The owner thereof has taken reasonable measures to keep such information secret; and
- The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

(b) Exchange of Information:

The Government may from time to time, disclose Government Confidential Information to the MCDC for use by the MCDC member entities or MCDC prime contractors, their subcontractors or suppliers, in connection with Government solicitations and similar processes or particular projects.

The CMF, on behalf of the MCDC, MCDC member entities, or MCDC prime contractors, their subcontractors or suppliers, may from time to time disclose information that is Trade Secret or Confidential Information to the Government in connection with a project proposal, or performance under this Order.

The prime contractor may from time to time disclose information that is Trade Secret or Confidential Information to the Government in connection with performance under this Order.

The prime contractor and/or Fujifilm may from time to time disclosure information that is Trade Secrete or Confidential Information to the Government in connection with performance under the Agreement or this Order.

Fujifilm and/or Supplier may from time to time disclosure information that is Trade Secret or Confidential Information in connection with performance under the Agreement or this Order.

(c) Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties, or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Sections pertaining to intellectual property rights (e.g., patents) and data rights, provided that the duty to protect such “Confidential Information” and “Trade Secrets” shall not extend to materials or information that:

- (i) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,
- (ii) Are not identified with a suitable notice or legend per the requirements in this Section 5.3,
- (iii) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof, as demonstrated by prior written records,
- (iv) Are or later become part of the public domain through no fault of the Receiving Party,
- (v) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,
- (vi) Are developed independently by the Receiving Party without use of Confidential Information, as evidenced by written records,
- (vii) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

(d) Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed except that each Receiving Party may retain one (1) copy of the Confidential Information solely to monitor its obligations under this Agreement. As used in

this section, tangible manifestations include human readable media, as well as magnetic and digital storage media.

- (e) Term: The obligations of the Receiving Party under this Article shall continue for a period of six (6) years from conveyance of the Confidential Information.
- (f) Flowdown. Supplier shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, and subawardees (including employees) at all levels, receiving such Confidential Information under this Order.

5.3 No publication without consent. No publication or presentation of information based on or developed under the Order is permitted except with Fujifilm's prior written consent, which may be withheld or conditioned in Fujifilm's sole discretion.

5.4 Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment.

Supplier understands that the Order is subject to the "Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment," incorporated through Attachment A below. Supplier agrees to comply with the terms of Attachment A, including the flow down requirements of Section F of Attachment A.

5.5 Liability of the Parties

- (a) Waiver of Liability. With regard to the activities undertaken pursuant to this Order, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.
- (b) Damages. The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

- (c) Extension of Waiver of Liability. Supplier agrees to extend the waiver of liability as set forth above to subawardees at any tier under an Order, by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this Order and the MCDC Base Agreement.
- (d) Applicability. Notwithstanding the other provisions of this Article, this Waiver of Liability shall not be applicable to:
 - (i) Claims between Fujifilm and the Supplier regarding a material breach or noncompliance;
 - (ii) Claims for damage caused by willful misconduct; and
 - (iii) Intellectual property claims.
- (e) Limitation of Liability. In no case shall Fujifilm, or Supplier's financial liability exceed the amount obligated by the Government under a PA. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

6. ADDITIONAL FLOWDOWN PROVISIONS APPLICABLE TO SUPPLIER GOODS AND/OR SERVICES FUNDED UNDER MCDC BASE AGREEMENT NO. 2022-417, PROJECT AGREEMENT NO. 01 ("MCDC Agreement No. 1"). In addition to the clauses set forth in Sections 2, 3 and 5 herein, the following shall apply to any Goods or Services funded by MCDC Agreement No. 1.

6.1. Intellectual Property

Applicability. This Section 6.1 applies only if Supplier's provision of Goods or Services are related to development of drug product under MCDC Agreement No. 01.

Awardee. "Awardee" shall mean Supplier unless the context requires otherwise.

- (a) The Awardee and the Government each retain any IP rights to their own materials, technical data (as defined in 48 DFARS 252.227-7013), technology, information, documents, or Know-How—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement ("Background IP"). Additionally, no Party to the Agreement will enter into an agreement with any contract manufacturer or other third party whereby the third party will obtain rights in Subject Inventions, as those terms are defined in this Agreement, absent the mutual consent of the Parties.

The Parties acknowledge that as of the Effective Date of this Project Agreement, they have Background IP as follows.

US Government Background IP: NONE

Fujifilm Background IP:

Background IP	Owner	Description
US9873891, WO2014177826A1, and any other patents, trade secrets, etc., included in the ApolloX™ license	Fujifilm	Apollo™ Expression System Patents, comprising Fujifilm's proprietary CHO DG44 dhfr(-/-) Host with Expression Vector, comprising an hEF1alpha Promoter, CHO Fibronectin Leader Sequences and a dhfr-Selectable Marker

Awardee Background IP: The Awardee shall notify Fujifilm of any Background IP that are related to research contemplated under the Order, in writing and prior to acceptance or fulfillment of the Order. The Awardee represents that, to the best of its knowledge, it has rights in the identified IP. For inventions which are the subject of patents/patent applications, the Awardee warrants that it has filed patent application(s), has issued patents, or is the assignee of issued patent(s) identified by Awardee, which contain claims that are related to research contemplated under this Agreement. No license(s) to any patent applications or issued patents identified as Background IP shall be granted under this Agreement.

Unless specified otherwise in this Agreement, no party relinquishes rights to any background patents to any other party under this Agreement.

- (b) Third Party Licenses. Besides third-party licenses that the Awardee has disclosed to Fujifilm and the Government in 6(a), the Awardee represents that no licenses or agreements it has or will have with any third party, will hinder or interfere with performance under this Agreement, or obligate the Government in any way other than what is specifically set forth in this Agreement, unless the Government agrees to same by modification to this Agreement.

- (c) Government Funding of Awardee Background IP. The Awardee represents that there was no Government funding of the Awardee Background IP, or of any research underlying the Awardee's Background IP.
- (d) Sufficient Rights. The Awardee represents to the best of its knowledge that the IP license(s) and other rights held by or granted to the Awardee, including but not limited to the rights in the patents and applications listed in 6(a) are sufficient to enable the Awardee to perform its obligations under this Agreement.
- (e) Subject Inventions. For any invention that is conceived or first actually reduced to practice ("Made") in the performance of this Agreement ("Subject Invention"), ownership of the Subject Invention, regardless of whether it is or is not patentable under U.S. patent law, will follow inventorship in accordance with U.S. patent law. The Parties represent and warrant that each inventor will assign his or her rights in any such Subject Inventions to his or her employing organization. If a Subject Invention is Made either by an Awardee employee ("Sole Awardee Subject Invention") or Made by a Government employee ("Sole Government Subject Invention"), the entire rights to that sole Awardee Subject Invention or Sole Government Subject Invention, will be respectively assigned to the Awardee or to the Government. If an Awardee employee and a Government employee jointly make a Subject Invention ("Joint Subject Invention"), it will be owned jointly by the Awardee and the Government. Ownership of Subject Inventions Made in whole or in part with sub-contractor or collaborator employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable sub-contractor collaborator.
 - (i) Sole Awardee Subject Invention. For each Sole Awardee Subject Invention, the Government will receive a non-exclusive, worldwide, non-transferable, paid-up, royalty-free, irrevocable license to practice the Subject Invention for Government purposes, and the right to sublicense same to third parties to practice the Subject Invention for Government purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval.
 - (ii) Inapplicability of Bayh-Dole Act. The Government acknowledges that the Bayh-Dole Act (35 U.S.C. §§ 200-212) does not apply to, nor govern, this Agreement or any Subject Inventions that may be Made hereunder. As such, the Government shall not have any rights to "march-in," as that term is defined in 35 U.S.C. § 203, and the Awardee is not subject to the manufacturing requirements of 35 U.S.C. § 204..

- (iii) Filing of Patent Applications. Each Party shall report any Subject Inventions with a DD 882 Form to the other Party within sixty (60) days of the time the inventor discloses it in writing to its personnel responsible for patent matters. If the Party reporting a Subject Invention is the Awardee, reporting will utilize the Interagency Edison (iEdison) system publicly available at <https://public.era.nih.gov/iedison>, and follow reporting instructions set forth in 37 CFR Section 401.14(c). The party having the right to retain title to, and file patent applications on, a specific Subject Invention, may elect not to file patent applications, provided it so advises the other Party within ninety (90) days from the date it reports the Subject Invention to the other Party, or at least ninety (90) days before a statutory bar date or public disclosure, whichever occurs earlier. Thereafter, the other Party may elect to file patent applications on the Subject Invention, and the Party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other Party. For Joint Subject Inventions, the Parties will consult with each other regarding the options for filing a patent application claiming a Joint Agreement Invention. Notwithstanding the above, no Party will disclose the Subject Invention in a public manner or in any way that may jeopardize patent rights, without written consent from the other Party.
- (iv) Executive Order No. 9424. Executive Order No. 9424 of 18 February 1944, requires all executive Departments and Agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.
- (v) Patent Expenses. The expenses attendant to the filing of patent applications shall be borne by the Party filing and/or prosecuting the patent application. Each Party shall provide the other party with copies of the patent applications it files on any Subject Invention, along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The Parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this Agreement.
- (vi) Patent Indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of,

or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of any performance under this Agreement or any deliverable provided by the Awardee to the Government under this Agreement, provided the Awardee is reasonably notified of such claims and proceedings and has been given such opportunity as is afforded by applicable laws, rules, or regulations to participate in its defense. Further, this indemnity shall not apply to –

1. An infringement resulting from compliance of the Awardee with specific written instructions of the Government directing a change in the design, processes, methodologies, specifications, or other aspects of the deliverable, or directing a manner of performance of the Agreement not normally used by the Awardee;
 2. An infringement resulting from addition to or change in the deliverable made by the Government subsequent to delivery or performance or use of the deliverable by the Government in a modified, unauthorized, or unintended form, or in combination with third-party technology or materials, if such infringement (or claim of infringement) would have been avoided, had such combination not occurred.
 3. An infringement resulting from violation of this Agreement by the Government; or an infringement resulting from the use of non-current versions of a provided deliverable by the Government, if such infringement (or claim of infringement) could have been avoided by use of such current version, provided that the Awardee delivered such superseding version or deliverable to the Government.
- (vii) Patent Enforcement. The Awardee will have the first option to enforce any patent rights covering a Joint Subject Invention at the Awardee's expense. If the Awardee chooses not to exercise this option, the Government may enforce patent rights covering a Joint Subject Invention.
- (viii) Patent Infringement Notice. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or

lawsuit, will be provided to the other at no cost to the requesting Party.

- (ix) No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for the Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

- (f) Flow Down. The Awardee shall flow down the requirements of this Section 6.1 to any subcontractors providing goods or services related to development of the Products

6.2. Data Rights

Applicability. This Section 6.2 applies only if Supplier's provision of Goods or Services are related to development of drug product under MCDC Agreement No. 01.

Awardee. "Awardee" shall mean Supplier unless the context requires otherwise.

Subject Data. "Subject Data" is defined as all Technical Data, as that term is defined in DFARS 252.227-7013(a)(15), which is generated by or on behalf of the Awardee in the performance of the Order. All Subject Data shall be owned by the Awardee. The Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement, within the Government and otherwise for "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16). The Government may, under a separate agreement or by modification to this Agreement, obtain any rights to use or disclose the Awardee's material or data, to the extent that such material or data was produced outside the scope of the Order. The Awardee agrees to retain and maintain in a clear and readable manner, until seven (7) years after completion or termination of this Agreement, all Subject Data. Collection, curation, and storage of the Study Data in the Government-issued standard, to be provided by the Government to the Awardee when developed and/or issued, for future transfer to the Government.

Background Technical Data Rights Assertions. "Background Data" shall mean all technical data, as defined in DFARS 252.227-7013, that exists prior to execution of the Order, or are developed outside the scope of this Agreement. The Awardee's Background Data includes, but is not limited to technical data as identified by Awardee in writing to Fujifilm prior to

acceptance or fulfillment of the Order, to the extent such data exists prior to execution of the Order or is developed outside the scope of the Order.

Marking of Data. The Awardee will mark any data delivered under this Agreement with the following legend: "Use, duplication, or disclosure is subject to the restrictions as stated in MCDC Base Agreement No. 2022-417, Project Agreement No. 01."

The Awardee may further mark data furnished with the rights specified in DFARS 252.227-7013 as "Limited Rights Data," "Government Purpose Rights Data," "Restricted Rights Software," or "Commercial-Rights Software," as appropriate. Any rights that the Awardee or the Government may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

All Technical Data and Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this Agreement with less than Unlimited Rights, shall be identified in reasonable specificity and particular rights granted [Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)]. If the data is marked "Limited Rights," the Awardee shall provide, upon request by the Government, an explanation to the Government as to why the data does not fall within the deliverables, and thus should not be accorded Unlimited Rights status.

Flow Down. The Awardee shall flow down the requirements of this Section 6.2 to any subcontractors providing goods or services related to development of the Products.

6.3. Regulatory Rights

Applicability. This Section 6.3 applies only if Supplier's provision of Goods or Services are related to development of drug product under MCDC Agreement No. 01.

Awardee. "Awardee" shall mean either Supplier or Fujifilm's customer who has contracted under MCDC Agreement No.1, as the context requires. It is not anticipated that Supplier will submit regulatory submissions in respect of drug substance or drug product; however, by way of clarity, "Awardee" shall mean Supplier for purposes of Section 6.3(g).

Background. The Agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA), and requires FDA pre-market approval or

clearance before commercial marketing may begin. It is expected this Agreement will result in the FDA clearance and commercialization of Product(s) in Section 3.0 of MCDC Agreement No. 1. The Awardee will be the Sponsor of any Regulatory Application (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 to the FDA) that controls research under this Agreement. The Sponsor of the Regulatory Application to the FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§ 3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

JPEO Regulatory Representative. The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND representative for all regulatory and quality activities.

This following clause protects the return on research and development investment made by the Government, in the event of certain regulatory product development failures related to the Products.

The Awardee agrees to the following:

- (a) The Awardee will provide to the Government all data, including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the Awardee will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded by this Agreement. The Government will review any such submissions promptly upon receipt. The Awardee will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The Awardee will keep the Government apprised of planned FDA meetings, and will invite the Government to planned FDA meetings. The Awardee will keep the Government apprised of all post-meeting outcomes relating to activities funded by this Agreement.
- (b) Communications. The Awardee will provide the Government with copies or documentation of all communications, both formal and informal, to or from the FDA, regarding the Products within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with the FDA.

- (c) Willful non-compliance or multiple occurrences of unintentional non-compliance with subsections “(i).” or “(ii).” of this clause, may result in termination of this Project Agreement.
- (d) Product Development Failure. Certain Product development failures may trigger certain remedies in Section “(v).” below for the Government. These remedies are not available to the Government for any cause outside of the following:
 - (i) this Agreement is terminated for nonperformance, or
 - (ii) the Awardee gives notice, required to be submitted to the Government no later than thirty (30) business days, of any formal management decision to terminate this Product development effort pre-market or to file for Federal bankruptcy protection.
- (e) If any of the Product development failures listed in Section “(d).” occur, the Awardee, upon the request of the Government:
 - (i) Excluding data that is jointly owned by the Parties, the Awardee shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Products, to the Government or its designee;
 - (ii) shall inform the FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under; and
 - (iii) solely to the extent reasonably necessary beyond the scope of the license granted to the Government under Section 6.3(c)(i), shall endeavor to negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any relevant and necessary Awardee Background IP related to the Products that is necessary for the Government to pursue commercialization of the Products with a third party
- (f) Public Law 115-92 Sponsor Authorization Letter. The Awardee shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling the FDA to disclose information to JPEO-CBRND (or other Government customer) and its Government support contractors, related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter was provided as part of the original RPP.

- (i) JPEO-CBRND (or other Government customer), in coordination with the Awardee, shall formally submit the executed letter to the FDA under the Regulatory Application, only if the proposed product becomes a Department of Defense (DoD) medical product priority under Public Law 115-92.
 - (ii) If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO-CBRND (or other Government customer) will include the Awardee in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO-CBRND or (other Government customer) will provide a summary of the interaction to the Awardee within ten (10) business days.
 - (iii) Deliverable(s): Public Law 115-92 Sponsor Authorization Letter.
- (g) Regulatory Compliance.
Awardee. "Awardee" shall
 - (i) GCP Compliance (as applicable). The Awardee shall maintain capabilities required to ensure full compliance with current Good Clinical Practices (GCP) when conducting clinical testing.
 - (ii) cGMP Compliance (as applicable). The Awardee shall maintain capabilities required to ensure full compliance with current Good Manufacturing Practices (cGMP) when manufacturing and testing products intended to be investigated or used in humans.
 - (iii) GLP Compliance (as applicable). The Awardee shall maintain capabilities required to ensure full compliance with Good Laboratory Practices (GLP) when conducting nonclinical studies which require GLPs.
- (h) Rights of Reference. The Awardee hereby grants to the Government and its permitted sublicensees a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended from time to time) to the Awardee's filings to the FDA. The Awardee shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government, for the limited purposes described above. The Awardee agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. The Government will agree to any reasonable request for information connected to

its reliance on the right of reference provided under this Section. This provision is in addition to any rights in technical data described earlier in this document.

- (i) **Continued Development of the Technology After Project Agreement Conclusion.** The Parties acknowledge that the Government has a requirement to develop the Technology in support of national defense, and accordingly, will need continued access to the Technology developed under this Project Agreement after the Project Agreement has concluded. Such access may occur through a subsequent agreement between the Parties, including but not limited to a follow-on production transaction, as contemplated in Section 1.3 of MCDC Agreement No.1, contingent on adequate funding and mutual agreement of the Parties to continue product development. The following rights will apply if the Parties are unable to reach such agreement for continued development.
 - (i) **IND Transfer.** At the end of the period of performance, upon mutual agreement of the Parties, the Awardee may transfer sponsorship of any Regulatory Application(s) for the Technology to the Government or its designee.
 - (ii) **Right of Reference and Market Exclusivity.** If the Parties do not mutually agree to transfer the IND as specified in the preceding paragraph, the Government may rely on its Right of Reference granted under Section 6.3(e), in order to continue development of the Technology with a third party. If the Awardee elects to also continue development of the Technology and achieves FDA licensure, the Awardee hereby agrees to waive any market exclusivity rights granted by the FDA, and to inform the FDA of the same for any medical countermeasure developed by the Government utilizing the aforementioned right of reference.
 - (iii) **If the Government desires to obtain additional rights in any Background IP owned by the Awardee, necessary to continue development of the Technology with a third party, the Parties will negotiate in good faith regarding the same.**
- (j) **Flow Down.** The Awardee shall flow down the requirements of this Section 6.3 to any subcontractors related to development of the Products.
- (k) **Survival.** This Section 6.3 will survive the acquisition or merger of the Awardee by or with a third party; will also be included in any subcontracts/sub-agreements relating to the development of the Products; and will survive the expiration of the Order or Agreement.

7. ADDITIONAL FLOWDOWN PROVISIONS APPLICABLE TO SUPPLIER GOODS AND/OR SERVICES FUNDED UNDER No. W15QKN-16-9-1002, AWARDED BY THE ACC-NJ TO THE MCDC (“MCDC AGREEMENT NO. 2”). In addition to the clauses set forth in Sections 2, 3 and 5 herein, the following shall apply to any Goods or Services funded by MCDC Agreement No. 2.

7.1. Publication

(a) Supplier shall not publish any information, data, presentations in any form or in any medium in respect of the work performed under the Order without Fujifilm’s prior written consent and in compliance with Fujifilm, prime contractor, CMF and MCDC requirements.

(b) In the event such consent is provided, parties to this Order are also responsible for assuring that every such approved publication of material based on or developed under this project contains the following disclaimer:

“The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government nor Sia Partners U.S., Inc. dba Latham BioPharm Group.”

(c) Supplier shall flowdown these requirements to its subawardees, at all tiers.

7.2. Intellectual Property, Data Rights, and Copyrights

Except as explicitly stated in this Section 7.2, the terms and conditions defined in the Base Agreement No. W15QKN-16-9-1002, and included in the MCDC Base Agreement No. 2021-452, regarding Intellectual Property, Data Rights, and Copyrights shall govern this Order, the Agreement (in respect of the Order) and any sub-agreement thereto funded by MCDC Agreement No. 2, and all such terms and conditions (including all rights of Supplier and its obligations to the Fujifilm and Government) shall flow-down from the Supplier to all its personnel, subcontractors, and representatives at all levels.

The following language shall replace and supersede Section 10.02 of the MCDC Base Agreement: The Supplier, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C. § 202. In the event that a Supplier consists of more than one entity or person, those entities or persons may allocate such right, title, and interest between themselves or others, as they may agree in writing. With respect to any Subject Invention in which the Supplier retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States (without a right to sublicense and/or utilize the Subject Invention for any

commercial activity), the Subject Invention throughout the world. For the sake of clear understanding and by way of example, such license shall not be used by the Government on its own behalf, or through a third party, to develop or offer any commercial product or service, including but not limited to contract drug development or manufacturing services.

The Supplier may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government. For the sake of clear understanding and by way of example, the use by the Government or any third party of products or processes that were used during the performance of the Project Agreement shall not be for the development or offering of any commercial product or service, including but not limited to contract drug development or manufacturing services.

The following language shall replace and supersede Section 10.05(1) of the MCDC Base Agreement: The Supplier shall retain a non-exclusive, royalty-free license with the right to grant sublicenses through multiple tiers throughout the world in each Subject Invention to which the Government obtains title, except if the Supplier fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. The Supplier's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the Supplier within the corporate structure of which the Supplier is a party and includes the right to grant licenses of the same scope to the extent that Supplier was legally obligated to do so at the time the Order was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

Supplier shall notify Fujifilm in writing and in advance of accepting or fulfilling the Order any and all pre-existing technical data and computer software with restrictions that may be used during performance of this Agreement. The Government shall receive Government Purpose Rights to all Technical Data and other Data (including computer software) developed and delivered under this Agreement, except for the pre-existing technical data and computer software that was previously developed exclusively at private expense and identified in writing in advance of accepting or fulfilling the Order to Fujifilm. To the maximum extent practicable, segregable portions of deliverables that will be restricted shall be clearly identified and labeled. If, after award, the Supplier wishes to use any other internally developed technical data or computer software, or any other pre-existing proprietary information not previously

identified in writing and in advance of accepting or fulfilling the Order, then the Supplier shall disclose its intent in writing to the MCDC CMF prior to its use and shall receive written approval from the Agreements Officer prior to proceeding. All technical data and computer software developed or delivered under this Agreement shall have appropriate data rights markings in accordance with DFARS 252.227- 7013(f) and 7014(f). The Supplier asserts that all Supplier owned or licensed Background Invention(s) or other intellectual property that affect the Government's rights in the deliverables anticipated under this Agreement are identified to Fujifilm in writing and in advance of accepting or fulfilling the Order.

- (a) **Regulatory Rights:** The Senior Director Medical Regulatory (SDMR) is the JPEO- CBRND representative for all regulatory and quality activities. The Supplier shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate. The Supplier shall invite the Fujifilm and SDMR to all FDA meetings and regulatory discussions applicable to this Order ,

This following protects the return on research and development investment made by the Government, in the event of certain regulatory product development failures related to the Technology.

Supplier agrees to the following:

- (i) The Supplier shall provide to the Government top-line summaries and key conclusions as described in Milestone Deliverables from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Project Agreement. Upon request, and unless subject to a claim of confidentiality or privilege by a third party, the Supplier shall provide the data underlying the top-line summaries and key conclusions referenced in this Section. In addition, the Supplier shall offer the Fujifilm and Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded by this Project Agreement. The Government will review any such submissions promptly upon receipt. The Supplier shall reasonably consider any comments provided by the Fujifilm and Government, and prior to submission shall provide notification to the Fujifilm and Government of any additional edits or revisions. The Supplier shall keep Fujifilm and Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Order.

- (ii) Communications. Supplier shall provide Fujifilm and Government with copies of all communications, both formal and informal, to or from FDA, regarding the Prototype Project Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with the FDA. In the event the Supplier receives communications from the FDA regarding the Prototype Project Technology related to a third-party product specific effort, the Supplier shall provide such communications suitably redacted allowing the Supplier to comply with its confidentiality requirements to the third-party.
- (b) Regulatory Compliance: Supplier shall comply with all applicable regulations, including but not limited to:
 - (i) GCP Compliance (as applicable). Supplier shall maintain capabilities required to ensure full compliance with current Good Clinical Practices (GCP) when conducting clinical testing.
 - (ii) cGMP Compliance (as applicable) Supplier shall maintain capabilities required to ensure full compliance with current Good Manufacturing Practices (cGMP) when manufacturing and testing products intended to be investigated or used in humans.
 - (iii) GLP Compliance (as applicable) Supplier shall maintain capabilities required to ensure full compliance with Good Laboratory Practices (GLP) when conducting nonclinical studies which require GLPs.
- (c) Audits and Inspections
 - (i) Government Audits. Supplier shall accommodate quality audit and site visits by Fujifilm, Fujifilm's customer in respect of MCDC Agreement No. 2, and/or Government of facilities of the Supplier or other subcontractors performing work in accordance with this Agreement. If the Government, Fujifilm, Fujifilm's customer in respect of MCDC Agreement No. 2, Supplier, or other party identifies any issues during an audit, Fujifilm shall capture the issues, identify potential solutions, and provide a report to the Government.
 - (ii) Quality Assurance (QA) Audits. The Government reserves the right to participate in QA audits performed by the Supplier. Upon completion of the audit/site visit, the Supplier shall provide a report capturing the findings, results and next steps in proceeding. If action is requested of a subcontractor, the Supplier shall provide

to Fujifilm and Government detailed concerns for addressing areas of nonconformance to FDA regulations for GMP guidelines, as identified in the audit report. The Supplier shall provide responses from the subcontractors to address these concerns and plans for corrective action.

- (iii) FDA Inspections. In the event of an FDA inspection that occurs in relation to the Technology set forth in this agreement, or for any other FDA inspection that has the reasonable potential to impact the performance of the Order, the Supplier shall provide Fujifilm and AOR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Supplier shall provide Fujifilm and AOR with copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plan's execution and a copy of all final responses to the FDA. The Supplier shall also provide copies of any FDA audits received from subcontractors that occur related to the Technology.

- (d) The Supplier shall flow down all Intellectual Property Rights, including all Patent Rights and Data Rights and all the Regulatory Requirements set forth herein to any Subcontractor(s) or other sub-agreement holder(s) related to development of technology funded by MCDC Agreement No.2.
- (e) This Section 7.2 shall survive the acquisition or merger of the Supplier by or with a third party. The above clauses shall survive the expiration of this Order.

7.3. Security & OPSEC (as applicable since Classification at PA Level)

Supplier shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, when applicable. Covered Defense Information (CDI) will be identified at the PA level. Supplier shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered

Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the Supplier's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016))). This

Order includes Controlled Unclassified Information (CUI). As such, DoD Manual 5200.01 (DoD Information Security Program: Protection of Classified Information) shall apply and all appropriate measures shall be followed. Supplier shall also comply with Distribution Statements, as mandated by DoDI 5230.24 (Distribution Statements on Technical Documents).

- (a) Throughout the life of the MCDC Base Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
 - (i) DoDM 5200.01, DoD Information Security Program, 24 Feb 12, Volumes 1-4
 - (ii) DoD 5200.2-R, Personnel Security Program, Jan 87
 - (iii) DoDD 5220.22, National Industrial Security Program, 28 Feb 06
 - (iv) DoD 5400.7-R, DoD Freedom of Information Act, Sept 98
 - (v) DoDI 2000.12, DoD Antiterrorism Program, 01 Mar 12
 - (vi) FAR Clause 4.402, Safeguarding Classified Information Within Industry
 - (vii) FAR Clause 52.204-2, Security Requirements, Aug 1996
- (b) The following statement shall be flowed to subrecipients to the Supplier.
 - (i) Classification guidance for requirement: "The security level for this agreement is Unclassified".
- (c) It is currently anticipated that Order performance will not occur in any Army controlled installation, facility or area, or access to Government information systems. Supplier shall agree to notify Fujifilm if performance on a Army controlled installation, facility or area, or access to Government information is anticipated. In such case, Parties shall negotiate in good faith to add necessary security terms to the Order prior to Supplier's performance in any Army controlled installation, facility or area.
- (d) Anti-Terrorism Awareness Training for Supplier Personnel Traveling Overseas. This standard language text requires U.S.-based Supplier and associated employees, to make available and to receive Government provided Area of Responsibility (AoR) specific AT Awareness Training as directed by AR 525-13. Specific AoR training content is directed by the combatant commander with the unit Anti-Terrorism Officer (ATO) being the local point of contact.

- (e) For Orders that require an OPSEC Standing Operating Procedure (SOP)/Plan. The Supplier shall develop an OPSEC SOP/Plan within ninety (90) calendar days of project award, to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security. This plan will be submitted by Fujifilm or Fujifilm's customer under MCDC Agreement No. 2 on behalf of the Supplier(s) to the AOR/AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it, and how to protect it. In addition, Supplier shall identify an individual who will be an OPSEC Coordinator. Supplier will ensure this individual becomes OPSEC Level II certified per AR 530-1.
- (f) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new Supplier employees assigned by the Supplier to perform under an Order must complete Level I OPSEC Awareness Training within thirty (30) calendar days of their reporting for duty. All Supplier employees performing under an OPSEC-designated project must complete annual Level I OPSEC Awareness Training. Level I OPSEC Awareness Training is available at the following website: <https://www.cdse.edu/catalog/elearning/GS130.html>.
- (g) For Projects Requiring Performance or Delivery in a Foreign Country. Incorporated in its entirety is DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S.
- (h) Work by the Supplier may involve access to CUI, as well as information classified as "Confidential," "Secret," or "Top Secret." The Supplier shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DoD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the Order security classification specification (DD form 254), if included, and (4) all security requirements, including but not limited to, OPSEC plans and those security requirements specific to the individual projects. During the course of the Order, the Parties may determine that information developed by the Supplier and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DoD 5220.22M.
- (i) Flowdown for OPSEC/Security Requirements:

The requirements delineated within this Section 7.4 shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

Attachment A

Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment.

This Article is to ensure compliance with Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232).

Based on the information provided below, the Government may be unable to enter into a new project agreement, exercise an option under an existing project, bilaterally modify a project agreement to extend the term of a project, execute an additional phase, or incrementally fund an existing project with the Member.

A. Definitions

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means—

- (1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);
- (2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);
- (3) Telecommunications or video surveillance services provided by such entities or using such equipment; or
- (4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the Government of a covered foreign country.

Critical technology means—

- (1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;
- (2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-
 - (i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or
 - (ii) For reasons relating to regional stability or surreptitious listening;
- (3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);
- (4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);
- (5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or
- (6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

B. Prohibition

(1) The Member is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless the Member is providing (i) a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or (ii) telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles, or the covered telecommunication equipment or services. A waiver, for a period not exceeding August 13, 2021, may be requested.

(2) The Member acknowledges and accepts that the Government is prohibited from entering into a new project agreement, exercising an option under an existing project, bilaterally modifying the project agreement to extend the term of a project, executing an additional phase, incrementally funding an existing project with the member or with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (b)(1) of this article applies, regardless of whether that use is in performance of work under a Federal contract or agreement.

C. Certification (to be completed upon Agreements Officer Request)

The Member shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for “covered telecommunications equipment or services.”

Based on that review:

- (1) ☐ The Member certifies that it does ☐ does not ☐ provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument.

- (2) If the Member does provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument as described in paragraph (c)(1), the Member certifies that it will ☐ will not ☐ provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument resulting from this solicitation. If the Member will provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument resulting from this solicitation (C)(2), the Member shall provide the additional disclosure information required at paragraph (D)(1) of this Article.
- (3) The Member certifies, after conducting a reasonable inquiry, for purposes of this certification, that it does ☐ does not ☐ use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. If the Member does use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services as described under this paragraph (C)(3), the Member shall provide the additional disclosure information required at paragraph (D)(2) of this Article.

D. Disclosures

(1) Disclosure for the certification in paragraph (C)(2) of this Article. If the Member does provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract, other transaction agreement, or other contractual instrument in in paragraph (C)(2) of this provision, the Member shall provide the following information:

(i) For covered equipment—

- a) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, Commercial and Government Entity (CAGE) code, and whether the entity was the Original Equipment Manufacturer (OEM) or a distributor, if known);
- b) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

- c) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(1) of this Article.

(ii) For covered services—

- a) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
- b) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(1) of this Article.

(2) If the Member does use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services in in paragraph (C)(3) of this Article, the Member shall provide the following information:

(i) For covered equipment—

- a) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);
- b) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
- c) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(2) of this Article.

(ii) For covered services—

- a) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

- b) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (B)(2) of this Article.

E. Reporting Requirement

(1) In the event the Member identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during agreement performance, or the Member is notified of such by a subcontractor at any tier or by any other source, the Member shall report the information in paragraph (E)(2) of this Article to the Agreements Officer and to the Department of Defense website at <https://dibnet.dod.mil>. The Member must notify the CMF that a report has been made.

(2) The Member shall report the following information pursuant to paragraph (E)(1) of this clause:

(i) Within one (1) business day from the date of such identification or notification: the agreement number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier CAGE code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within ten (10) business days of submitting the information in paragraph (E)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Member shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

F. Subcontracts

The Member shall insert the substance of this article, including this paragraph (F) and excluding paragraph (B)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items