

**Additional Terms and Conditions Applicable to Agreements Funded in whole or in part  
by the U.S. Government**

For transactions involving funds provided through a United States Government (“U.S. Government”) contract, the clauses set forth below are hereby incorporated into the agreement for services/products with PPD (“Agreement”) with the same force and effect as if they were included in full text.

**1. General.** While PPD has made every effort to include every potentially applicable U.S. Government contract clause in these additional terms and conditions, any U.S. Government contract clauses, the inclusion of which in the Agreement is mandatory under a statute or regulation, shall be considered to be included by operation of law, even if the clause has been omitted from the Agreement. Notwithstanding the foregoing, such terms are self-deleting where not applicable to the Services provided.

Vendor shall indemnify and hold PPD harmless from and against any cost, price reduction, withholding, offset, penalty, interest, claim, demand, determination of unallowability or unallocability, or any other civil, criminal, or administrative liability, whether arising under statute, regulation, contract, or common law, and shall reimburse PPD for all of its damages and associated costs, including reasonable attorney fees and other expenses, if said liability is attributable to the Vendor or Vendor’s suppliers’ failure to comply with the applicable U.S. Government contract clauses.

Vendor shall incorporate the applicable U.S. Government contract clauses in each lower-tier subcontract placed in support of this Agreement. Upon request, Vendor shall provide relevant documentation to support Vendor’s assertion that its Goods or Services satisfy the definition of “commercial products” and/or “commercial services” under FAR 2.101.

**2. Financial Conflicts of Interest.** Vendor agrees to comply with the applicable requirements of 45 CFR Part 94 or any local equivalent. Vendor certifies that it maintains a policy that requires compliance with these requirements. Vendor shall report all identified financial conflicts of interests to PPD within five (5) business days of discovering the conflict and submit with this report a mitigation plan for PPD’s review and approval. PPD reserves the right to terminate this Agreement or require removal of Vendor’s employee or lower-tier subcontractor as a result of a financial conflict of interest. Failure to comply with these requirements is a material breach of the Agreement.

**3. U.S. Government Right to Inspect.** Vendor recognizes that the U.S. Government has the right to inspect and test all work conducted under this Agreement and all facilities used to perform such work, to the extent practicable at all places and times, including the period of performance of such work and in any event before its termination.

**4. Subcontract Reporting.** Vendor acknowledges that U.S. federal law requires PPD to report information on subcontract awards and requires all reported information be made public. To satisfy such reporting requirements, upon PPD’s request, Vendor shall provide PPD with the subcontract number, Vendor unique entity identifier, the number of direct labor hours expended on the services performed during the previous Government fiscal year, and other information required to satisfy PPD’s reporting obligations under Federal law. No confidentiality provision under this Agreement may be construed to prohibit or otherwise restrict Vendor, as a subcontractor of PPD under a U.S. Government contract, from lawfully reporting fraud, waste, or abuse to a designated investigative or law enforcement representative.

**5. Certificate of Confidentiality.** Vendor shall protect the privacy of individuals who are the subject of a U.S. Government-funded research in accordance with Section 301(d) of the Public Health Service Act, the NIH Policy for Issuing Certificates of Confidentiality NOT-OD-17-109 (available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>), and any other applicable regulations or guidance.

**6. Representations.** Vendor represents and warrants that he/she/it or any of Vendor’s principals:

- a) are not presently debarred, suspended, proposed for debarment/suspension, or declared ineligible for the award of contracts by any Federal agency;
- b) have not within the last three years from the effective date of this Agreement, been convicted of, or had a civil judgment rendered against it/him/her and/or any of Vendor's principals, for any of the following:
  - i. the commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a federal, state or local government contract or agreement;
  - ii. a violation of U.S. federal or state antitrust statutes relating to the submission or offers; or
  - iii. the commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property;
- c) are not presently indicted for, or otherwise criminally or civilly charged by a U.S. Government entity with, commission of any of the preceding offenses, and
- d) have not, within a three-year period from the effective date of this Agreement, been notified of any delinquent Federal taxes in an amount for which the liability remains unsatisfied.

Vendor represents and warrants that he/she/it or any of Vendor's principals will not give, offer, solicit, accept or induce any money, fees, commissions, credit, gifts, gratuities, things of value, or compensation of any kind to U.S. Government, PPD, or any other subcontractor related to this Agreement, or any employees, agents or subcontractors of U.S. Government or PPD for purposes of getting favorable treatment under this Agreement.

Vendor certifies, represents and warrants that he/she/it or any of Vendor's principals have not and will not use any funds received under this Agreement to influence or attempt to influence an officer or employee of any governmental agency, or a member, officer, or employee of the U.S. Congress, or an employee of a member of the U.S. Congress to award, extend, renew, amend, modify or enter into any U.S. Government contract, grant, loan, or cooperative agreement. If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a federal contract, grant, loan, or cooperative agreement, Vendor must complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

Where Vendor is providing clinical services support as part of a clinical trial, Vendor represents and warrants that he/she/it has, within the past three years, provided training in Good Clinical Practices to the clinical trial staff, consistent with the principles of the International Conference on Harmonisation (ICH) E6 (R2). Vendor will provide completion of training documentation to PPD upon request. Vendors providing clinical services in support of a clinical trial shall further comply with all applicable U.S. Government regulation, guidance and policies relating to research patient care costs.

If, during the term of this Agreement, Vendor or any of Vendor's principals is in breach of any of the above representations or warranties, Vendor shall immediately notify PPD in writing of such event, and PPD shall have the right to terminate this Agreement upon notice to Vendor.

**7. Loss and/or Disclosure of Personally Identifiable Information (PII) - Notification of Data Breach.** Vendor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the PPD Project Lead/Management within one (1) hour of discovering the incident. Vendor agrees to cooperate with PPD to provide all information related to the incident that is requested and as necessary to limit, stop, mitigate, or respond to the data breach.

**8. Storage Facility Requirements.** If any materials are generated under this Agreement for which commercial records storage is required, Vendor shall ensure that such materials shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

**9. Controlled Unclassified Information.** To the extent Vendor access, stores, generates, or handles Controlled Unclassified Information (CUI) (as defined below) in performance of this Agreement, Vendor shall comply with applicable policies and guidance for the storage, processing, handling, or generation of CUI. CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Vendor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. As implemented, the term "handling" refers to "...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute shall be:

- i. Marked appropriately;
- ii. Disclosed to authorized personnel on a Need-To-Know basis;
- iii. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and
- iv. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

**10. Prohibition On Vendor Involvement With Terrorist Activities.** Vendor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Vendor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Agreement.

**11. Secure Software Development Practices.** Vendor shall ensure that Software Products are developed in accordance with the requirements of the current version of the Secure Software Development Framework (SSDF) Appendix ("**SSDF Appendix**") set forth at Appendix 1, as may be modified or amended from time to time. Within five (5) business days of PPD's written request (email is sufficient), Vendor shall complete a written attestation of compliance with SSDF Appendix in a format provided by PPD. Vendor warrants that all requirements set forth in the SSDF Appendix are consistently maintained and satisfied throughout the term of the Agreement and it shall immediately notify PPD in writing if Vendor no longer complies with any requirements of the SSDF Appendix. If there is a conflict between the SSDF Appendix and the Agreement, the SSDF Appendix shall govern and control in matters covered by the SSDF Appendix. For purposes of this clause, "**Software Products**" refers to software, firmware, operating systems, applications, and application services (e.g., cloud-based software), including software contained in a product, any major software revision, or any hosted service that deploys continuous updates.

**12. Federal Acquisition Regulation ("FAR"), Health and Human Services Acquisition Regulation ("HHSAR") and Department of Defense ("DoD") FAR Supplement ("DFARS") Clauses.** The FAR, HHSAR, and DFARS clauses set forth below are hereby incorporated by reference in this Agreement with the same force and effect as if they were included in full text. The version of each clause shall be the version in effect as of the date of this Agreement.

As used in these clauses: (1) “commercial product” and “commercial service” shall have the same meanings as defined in FAR 2.101; (2) “Contract” means this Agreement; (3) “Contracting Officer” shall mean the PPD contract representative ; (4) “Contractor” in these clauses shall be deemed to refer to Vendor; (5) “subcontract” means any contract placed by Vendor or lower-tier subcontractors under this Agreement; and (6) “Simplified Acquisition Threshold” or “SAT” shall have the meaning set forth in version of FAR 2.101; where such meaning is consistent with a reasonable interpretation of the provision which properly expresses the relationship between PPD and Vendor. For the avoidance of doubt, 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, and (2) when title to property is to be transferred directly to the U.S Government.

Vendor shall incorporate all applicable FAR, DFARS, and/or HHSAR clauses into its lower tier contracts in accordance any flow down requirements specified in such clauses. If there is a conflict with or addition to a clause in effect on the Agreement date and a clause of PPD’s U.S. Government Contract, the U.S. Government Contract clause shall govern.

The full text of such clauses incorporated by reference shall be made available to Vendor at its request and can be accessed at <https://www.acquisition.gov/>.

#### 12.a. Clauses Applicable to All Agreements

Clause No.	Title	Notes
52.202-01	Definitions	
52.203-13	Contractor Code of Business Ethics and Conduct	Agreements over \$6M and with a performance period >120 days
52.203-15	Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009	Agreements funded under the Recovery Act
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	Does not apply to Agreements for commercially available off-the-shelf items
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment	Paragraph (b)(2) does not apply
52.204-27	Prohibition on a ByteDance Covered Application	
52.209-6	Protecting the Government’s Interests When Subcontracting with Contractors Debarred, Suspended or Proposed for Debarment	Agreements over \$35,000
52.219-8	Utilization of Small Business Concerns	If the Agreement offers subcontracting opportunities; applies only to U.S. entities
52.219-28	Post-Award Small Business Program Re-representation	If Vendor does not have representation and certifications in SAM
52.222-3	Convict Labor	

Clause No.	Title	Notes
52.222-21	Prohibition of Segregated Facilities	Where 52.222-26, Equal Opportunity applies
52.222-26	Equal Opportunity	Agreements over \$10,000; applicable to work performed within the U.S.
52.222-35	Equal Opportunity for Veterans	Agreements over \$150,000; applicable to foreign agreements where work will be performed by employees who were recruited within the U.S.
52.222-36	Equal Opportunity for Workers with Disabilities	Agreements over \$15,000; applicable to foreign agreements where work will be performed by employees who were recruited within the U.S.
52.222-37	Employment Reports on Veterans	Agreements over \$150,000; applicable to foreign agreements where work will be performed by employees who were recruited within the U.S.
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Agreements over \$10,000 that will be performed within the U.S.
52.222-41	Service Contract Labor Standards	Agreements subject to the Service Contract Labor Standards
52.222-50 & Alt. I	Combating Trafficking in Persons	
52.222-51	Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements	Applies to for maintenance, calibration, or repair of commercial products/equipment.
52.222-53	Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services – Requirements	Applies to any services regularly offered to non-governmental customers, at established market prices, and by employees who spend <20% of their time during a month period servicing U.S. Government agreements
52.222-54	Employment Eligibility Verification	Agreements over \$3,500 for any work performed inside the U.S.
52.222-55	Minimum Wages for Contractor Workers under Executive Order 14026	Agreements subject to the Service Contract Labor Standards statute and performed within the U.S.
52.222-62	Paid Sick Leave Under Executive Order 13706	Agreements subject to the Service Contract Labor Standards statute and performed within the U.S.
52.224-3 & Alternate I	Privacy Training	If Vendor will have access to, or will design, operate, develop, or maintain a system of records or will create, collect, use, or otherwise handle personally identifiable information
52.225-13	Restrictions on Certain Foreign Purchases	
52.226-6	Promoting Excess Food Donation to Nonprofit Organizations	Agreements for provision of food within the US

Clause No.	Title	Notes
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	If Vendor is a small business subcontractor
52.242-15	Stop-Work Order	Paragraphs (c) and (d) do not apply
52.244-6	Subcontracts for Commercial Items	
52.247-64	Preference for Privately Owned U.S.-Flag Commercial Vessels	For supplies shipped by ocean vessels

#### 12.b. Additional Clauses Applicable to Agreements for Non-Commercial Products or Services

Clause No.	Clause Title	Notes
52.203-6	Restrictions on Subcontractor Sales to the Government	Agreements over the SAT
52.203-7	Anti-Kickback Procedures	Agreements over the SAT
52.203-14	Display of Hotline Posters	Agreements more than \$6 million performed wholly or partly within the U.S.
52.203-16	Preventing Personal Conflicts of Interest	
52.203-17	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights	Agreements over the SAT
52.208-8	Required Sources for Helium and Helium Usage Data	Any Agreements involving a major helium requirement
52.215-14	Integrity of Unit Prices	Agreements over the SAT
52.223-18	Encouraging Contractor Policies to Ban Text Messaging While Driving	Agreements over \$10,000
52.224-2	Privacy Act	Where Vendor will design, develop or operate a system of records on individuals containing personally identifiable information (PII) or protected health information (PHI)
52.226-6	Promoting Excess Food Donation to Nonprofit Organizations	Agreements over \$30,000 for the provision, service, or sale of food in the U.S.
52.227-1	Authorization and Consent	Agreements over the SAT
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Agreements over the SAT
52.227-10	Filing of Patent Applications—Classified Subject Matter	Agreements involving classified subject matter
52.227-11	Patent Rights—Ownership by the Contractor	Agreements for R&D to be performed by a small business or nonprofit Vendor; references to the “Government” are unchanged
52.227-14	Rights in Data – General	Not applicable to Agreements performed entirely outside the U.S. Alt IV shall apply to academic institutions
52.227-16	Additional Data Requirements	
52.230-2	Cost Accounting Standards	Agreements subject to the CAS
52.230-3	Disclosure and Consistency of Cost Accounting Practices	Agreements over \$750,000
52.230-5	Cost Accounting Standards—Educational Institution	Agreements with educational institutions

Clause No.	Clause Title	Notes
52.230-6	Administration of Cost Accounting Standards	
52.237-7	Indemnification and Medical Liability Insurance	All Agreements for nonpersonal healthcare services; insert "\$10,000,000" in paragraph (a)
52.245-1	Government Property	Where Vendor receives U.S. Government provided property or acquires property subject to this clause. Alt II shall apply to academic institutions
52.236-13	Accident Prevention	
52.246-16	Responsibility for Supplies	
52.247-63	Preference for U.S.-Flag Air Carriers	To the extent personnel or property will be transported via air carrier

**Modified clauses included in full text:**

FAR Clause **52.224-1, Privacy Act Notification** (April 1984). Applies to Agreements that require the design, development or operation of a system of records containing PII or PHI.

Vendor will be required to design, develop, or operate a system of records on individuals, to accomplish an agency function subject to the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 U.S.C.552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

**12.c. Additional Clauses Applicable to Cost-Type Agreements, Time & Materials Agreements, or Agreements for which Certified Cost or Pricing Data is Provided**

Clause No.	Clause Title	Notes
52.215-2	Audit and Records—Negotiation	Agreements over the SAT
52.215-12	Subcontractor Cost or Pricing Data	Where certified cost/pricing data is required
52.215-13	Subcontractor Certified Cost or Pricing Data—Modifications	Where certified cost/pricing data is required
52.215-15	Pension Adjustments and Asset Reversions	
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions	
52.215-19	Notification of Ownership Changes	
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications	Alt IV may apply
52.215-23	Limitations on Pass-Through Charges	Agreements over the SAT
52.229-8	Taxes – Foreign Cost- Reimbursement Contracts	Where Vendor receives a foreign tax credit that reduces its Federal income tax liability because of the payment of any tax or duty that was reimbursed under this Agreement; paragraph (a) does not apply
52.242-3	Penalties for Unallowable Costs	

Clause No.	Clause Title	Notes
52.247-67	Submission of Transportation Documents for Audit	

- 12.c.i. Dissemination of False or Deliberately Misleading Information.** Vendor shall not use contract funds to disseminate information that is deliberately false or misleading.
- 12.c.ii. Restriction on Pornography on Computer Networks.** Vendor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.
- 12.c.iii. Gun Control.** Vendor shall not use contract funds in whole or in part, to advocate or promote gun control.
- 12.c.iv. Hotel and Motel Fire Safety.** Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic. Public accommodations that meet the requirements can be accessed at: <http://apps.usfa.fema.gov/hotel/>.
- 12.c.v. Use of Funds for Conferences, Meetings and Food.** Vendor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this Agreement without prior written PPD approval. In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.
- 12.c.vi. Use of Funds for Promotional Items.** Vendor shall not use contract funds to purchase promotional items. Promotional items include but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

**12.d. Health and Human Services Acquisition Regulations (HHSAR) Clauses Applicable to Agreements funded under a Department of Health and Human Services Contract**

Clause No.	Clause Title	Notes
352.208-70	Printing and Duplication	
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Agreements where FAR 52.222-26 equal opportunity applies
352.223-70	Safety and Health	Where Agreement involves toxic substances, hazardous materials, or hazardous operations
352.224-70	Privacy Act	Agreements that require the design, development or operation of a system of records containing PII or PHI
352.227-11	Patent Rights - Exceptional Circumstances	Agreements for experimental, developmental, or research work
352.227-14	Rights in Data – Exceptional Circumstances	



Clause No.	Clause Title	Notes
352.208-70	Printing and Duplication	
352.227-70	Publications and Publicity	Where Vendor may propose publishing the results of its work
352.231-70	Salary Rate Limitation	Agreements that are fixed-price level-of-effort or labor-hour. The salary rate limitation also applies to individuals
352.237-74	Nondiscrimination in Service Delivery	
352.239-74	Electronic and Information Technology Accessibility	Where Vendor provides electronic or IT products or services
352.270-4b	Protection of Human Subjects	Agreements where humans are involved
352.270-5b	Care of Live Vertebrate Animals	Agreements where animals are involved
352.270-6	Restriction on Use of Human Subjects	Agreements where humans are involved
352.270-12	Needle Exchange	Cost-type or T&M agreements only
352.270-13	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research	Cost-type or T&M agreements only

**12.d.i. Record Management and Retention.** Vendor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/NIH policies and shall not dispose of any records unless authorized by HHS/NIH. In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/NIH policies.

**12.e. Department of Defense (DoD) FAR Supplement (DFARS) Clauses Applicable to Agreements funded under a Department of Defense Contract**

Clause No.	Clause Title	Notes
252.203-7001	Prohibition on Persons Convicted of Fraud or Other Defense Contract-Related Felonies	Agreements over the SAT where PPD is contracted directly with the U.S. Government; does not apply to commercial items
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	
252.203-7004	Display of Fraud Hotline Posters	Agreements over \$6M
252.204-7000	Disclosure of Information	Does not apply to commercial items
252.204-7012	Safeguarding of Unclassified Controlled Technical Information	Agreements involving a covered information system
252.204-7015	Notice of Authorized Disclosure of Information for Litigation Support	
252.204-7018	Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services	
252.211-7003	Item Identification and Valuation	Vendor's obligations under this clause are limited to cooperating with PPD's efforts to comply with this clause, including granting PPD access to Vendor's deliverables at its facilities and to appropriate property records

Clause No.	Clause Title	Notes
252.225-7033	Waiver of United Kingdom Levies	Agreements for supplies where a lower-tier subcontract exceeding \$1M with a U.K. firm is anticipated
252.225-7048	Export-Controlled Items	
252.226-7001	Utilization of Indian Organizations and Indian Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	Agreements over \$500,000
252.227-7013	Rights in Technical Data – Noncommercial Items	Applies to the extent any data developed in any part at U.S. Government expense; no Vendor assertions are made under this clause. Does not apply to commercial items
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	Where Vendor will provide computer software or computer software documentation
252.227-7015	Technical Data – Commercial Items	Applies to technical data pertaining to a commercial item developed exclusively at private expense; does not apply to noncommercial items
252.227-7016	Rights in Bid or Proposal Information	Applies to Vendor information submitted in a proposal to the U.S. Government
252.227-7019	Validation of Asserted Restrictions – Computer Software	Where Vendor will be supplying computer software to the U.S. Government
252.227-7037	Validation of Restrictive Markings on Technical Data	Agreements requiring delivery of technical data
252.227-7038	Patent Rights—Ownership by the Contractor (Large Business)	Where Vendor is a large business and Agreement is for experimental, developmental, or research work; references to “Government” remain unchanged
252.235-7002	Animal Welfare	Agreements involving live vertebrate animals
252.235-7004	Protection of Human Subjects	Agreements involving human subjects (does not apply to research involving only the use of cadaver materials)
252.239-7010	Cloud Computing Services	Applies to Agreements involving or that may involve cloud computing services
252.244-7000	Subcontracts for Commercial Items	
252.247-7023	Transportation of Supplies by Sea	All paragraphs apply to Agreements over the SAT; only Paragraphs (a) through (e) apply to Agreements below the SAT

## Appendix 1

### Secure Software Development Framework (SSDF)

In accordance with Executive Order (EO) 14028, Improving the Nation's Cybersecurity (May 12, 2021)<sup>1</sup> and OMB Memorandum M-22-18 (September 14, 2022)<sup>2</sup>, all Software Products provided to Thermo Fisher or its customers pursuant to a contract or purchase order issued by Thermo Fisher shall be in compliance with the standards set forth in below. These requirements are excerpted from NIST SP 800-218, Secure Software Development Framework (SSDF) Version 1.1: Recommendations for Mitigating the Risk of Software Vulnerabilities.<sup>3</sup>

These requirements apply to all software firmware, operating systems, applications, and application services (e.g., cloud-based software), as well as products containing software,<sup>4</sup> that have been developed or modified by major version changes (e.g., using a semantic versioning schema of Major.Minor.Patch, the software version number goes from 2.5 to 3.0) on or after September 14, 2022.

#### 1) Protect the Organization

The software was developed and built in secure environments. Those environments were secured by the following actions, at a minimum:

- a) Separating and protecting each environment involved in developing and building software;
- b) Regularly logging, monitoring, and auditing trust relationships used for authorization and access:
  - i. to any software development and build environments; and
  - ii. among components within each environment;
- c) Enforcing multi-factor authentication and conditional access across the environments relevant to developing and building software in a manner that minimizes security risk;
- d) Taking consistent and reasonable steps to document, as well as minimize use or inclusion of software products that create undue risk, within the environments used to develop and build software;
- e) Encrypting sensitive data, such as credentials, to the extent practicable and based on risk;
- f) Implementing defensive cyber security practices, including continuous monitoring of operations and alerts and, as necessary, responding to suspected and confirmed cyber incidents;

#### 2) Protect the Software

The software producer has made a good-faith effort to maintain trusted source code supply chains by:

- a) Employing automated tools or comparable processes; and
- b) Establishing a process that includes reasonable steps to address the security of third-party components and manage related vulnerabilities;

#### 3) Produce Well-Secured Software

The software producer maintains provenance data for internal and third-party code incorporated into the software;

#### 4) Respond to Vulnerabilities

The software producer employed automated tools or comparable processes that check for security vulnerabilities. In addition:

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<sup>1</sup> Available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/05/12/executive-order-on-improving-the-nations-cybersecurity/>

<sup>2</sup> Available at <https://www.whitehouse.gov/wp-content/uploads/2022/09/M-22-18.pdf>

<sup>3</sup> Available at <https://csrc.nist.gov/pubs/sp/800/218/final>

<sup>4</sup> See <https://www.nist.gov/system/files/documents/2022/02/04/software-supply-chain-security-guidance-under-EO-14028-section-4e.pdf>

- a) The software producer ensured these processes operate on an ongoing basis and, at a minimum, prior to product, version, or update releases and
- b) The software producer has a policy or process to address discovered security vulnerabilities prior to product release; and
- c) The software producer operates a vulnerability disclosure program and accepts, reviews, and addresses disclosed software vulnerabilities in a timely fashion.