AGREEMENT #: W81XWH1810606 FLOWDOWN REQUIREMENTS FOR SUBCONTRACTS
(Appendix A)

In Appendix A, "Subcontractor" means the "Supplier" and "Subcontract" means this "Agreement." Subcontractor understands and acknowledges that MedImmune is performing an agreement with the US Army Medical Research Acquisition Activity (USAMRAA) of the Department of Defense (DOD) of the United States Government (Government), Agreement # W81XWH1810606.

GOVERNMENT SUBCONTRACT:

As a prime contractor to DOD, MedImmune must comply with specific provisions of the Agreement, including ensuring that any subcontractors supporting MedImmune comply with the terms in the Agreement that flow down to subcontractors.

Supplier understands and acknowledges that the work required under this Agreement will be performed in support of MedImmune's Contract with US Army Medical Research Acquisition Activity (USAMRAA) of the Department of Defense of the United States Government (Government), Agreement # W81XWH1810606. When providing services for MedImmune under this Agreement, the Supplier (Subcontractor) must meet certain MedImmune's requirements under its prime contract with Government. Therefore, work performed under this Agreement is considered a second-tier federal government subcontract.

As a Subcontractor under the W81XWH1810606, the Subcontractor must adhere to all applicable federal procurement regulations and other pertinent requirements set forth in this Appendix. Subcontractor confirms that it is eligible to perform subcontracting work under a government contract and agrees with Flowdowns attached in this Appendix. Further, to the extent the Subcontractor must enter into subcontracts to fulfil requirements of this Agreement or any service hereunder W81XWH1810606, Subcontractor shall take full responsibility to ensure that its subcontracts are in full compliance with all applicable Federal procurement laws and regulations and pertinent subcontract requirements, as set in this Appendix.

Should any of the terms and conditions contained in Appendix A contradict those elsewhere in the Agreement, or any Statement of Work under the Agreement, then the terms and conditions of Appendix A shall supersede all others.

Subcontractor acknowledges and understands that the Government is a third-party beneficiary to this Agreement and is entitled to the rights and benefits hereunder and may enforce the provisions hereof as if it were a party hereto.

CONFIDENTIAL INFORMATION

Subcontractor further understands and agrees that MedImmune may provide Confidential Information in regards to this Agreement (including information exchanged pursuant to an existing confidentiality or nondisclosure agreement) to representatives or agents of the U.S. Government in connection with MedImmune's prime Agreement W81XWH1810606. MedImmune takes commercially reasonable steps to restrict their disclosure by the U.S. Government under applicable public disclosure / transparency laws. MedImmune, however, shall have no liability for the U.S. Government's release of any Subcontractor Confidential Information.

COMMUNICATION

Any Communication/notification required under this Agreement from/to the Subcontractor to/from Government shall be made through MedImmune.

EQUAL OPPORTUNITY EMPLOYER

MedImmune is an equal employment opportunity employer and is a federal contractor. Consequently, the Parties agree that, to the extent applicable, they will comply with Executive Order 11246, as amended (41 C.F.R. Part 60-1); the Vietnam Era Veterans Readjustment Assistance Act of 1974; and Section 503 of the Vocational Rehabilitation Act of 1973; and 48 C.F.R. 52.219-9 "Subcontracting Plan Regarding Small Business Concerns" and also agree that these laws are incorporated herein by this reference. The Parties also agree to comply with any applicable provisions of Executive Order 13496 (29 C.F.R. Part 471), relating to the notice of employee rights under federal labor laws and abide by the requirements of 41 C.F.R. §§ 60-1.4(a) (affirmative action and EEO for women and minorities); 60-300.5(a) (affirmative action and EEO for certain classes of covered veterans); and 60-741.5(a) (affirmative action and EEO for certain classes of individuals with a disability), which are incorporated into this contract by reference (if applicable).

MedImmune and the US Government have entered into Agreement that obligates MedImmune to provide equal opportunities for small business concerns to engage in the performance of MedImmune's Agreement. In addition, MedImmune is obligated to include the language of 48 C.F.R. 52.219-8 "Utilization of Small Business Concerns" in all MedImmune contracts that offer further subcontracting opportunities. If: (i) the Purchase Order offers further subcontracting opportunities, (ii) Subcontractor is not a small business concern, and (iii) the amount to be paid to Subcontractor under this Purchase Order is Seven Hundred Thousand Dollars ($700,000) or more (or if the annual cumulative amount of this Purchase Order and all other agreements, including statements of work, and contracts with Subcontractor equals or exceeds Seven Hundred Thousand Dollars ($700,000)), then Subcontractor will implement a small business subcontracting plan ("**Subcontracting Plan**") pursuant to 48 C.F.R. 42.219-9, Subcontracting Plan Regarding Small Business Concerns. A sample plan is located at: https://www.medimmune.com/content/medimmune/government-contract-t-cs.html. Upon MedImmune's request, Subcontractor will provide to MedImmune a copy of such Subcontracting Plan, and updates as requested.

Subcontractor certifies that Subcontractor and/or any of its Principals, (as defined in 48 C.F.R. 52.209-5) are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency.

PUBLICATION, ACKNOWLEDGEMENT, AND PUBLIC RELEASE

There shall be no dissemination of information or publication regarding the work performed under this Agreement without prior written approval by MEDIMMUNE.

PATENTS AND INVENTIONS REPORTING REQUIREMENTS

Subcontractor must report to MedImmune annually any inventions made during the year while conducting work under this Agreement.

PROPERTY ACQUIRED WITH AGREEMENT FUNDS

Subcontractor must provide to MEDIMMUNE a cumulative listing of nonexpendable property acquired with this Agreement funds, if applicable.

APPLICABLE LAW

United States federal law will apply to the construction, interpretation, and resolution of any disputes arising out of or in connection with this Appendix.

FLOWDOWNS:

Terms and Conditions Incorporated by Reference

As a Prime Contractor to the US Government, MEDIMMUNE is subject to below terms and conditions. As a Subcontractor under MEDIMMUNE Prime Contract with USAMRAA, Agreement # W81XWH1810606, the Supplier is subject to the below provisions to the extent they apply to Subcontractor.

Chapter I, Subchapter C of Title 32, Code of Federal Regulations (CFR), "DoD Grant and Agreement Regulations" (DoDGARs), parts 26, 28, 34, 37, and 1125, incorporated herein by reference.

Guidance in 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," as modified and supplemented by the Department of Defense's (DoD) interim implementation found at 2 CFR Part 1103, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR Part 200" (79 FR 76047, December 19, 2014), are incorporated herein by reference.

For for-profit organizations and those non-profit organizations identified in Appendix VIII to 2 CFR part 200, "Nonprofit Organizations Exempted From Subpart E – Cost Principles," the cost principles in part 31 of Chapter 1 of Title 48, CFR, "Federal Acquisition Regulation" (FAR), and part 231 of Chapter 2 of Title 48, "Department of Defense FAR Supplement," are incorporated herein by reference.

Division III - USAMRAA General Research Terms and Conditions with For-Profit Organizations (effective February 2017), are incorporated herein by reference. They are available at http://www.usamraa.army.mil/index.cfm?ID=12&Type=3 .

Prohibition of Use of Laboratory Animals (NOVEMBER 2015)

Notwithstanding any other terms and conditions contained in this Agreement or incorporated by reference herein, the Subcontractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Furthermore, modifications to already approved protocols require approval by ACURO prior to implementation. For each fiscal year, the Subcontractor must maintain, and upon request from MEDIMMUNE or ACURO, submit animal usage information.

Noncompliance with any of these terms and conditions may result in withholding of funds and/or the termination of the Agreement.

The Animal Care and Use Office requirements can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro.

Prohibition of Use of Human Subjects (NOVEMBER 2015)

Research under this Agreement involving the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, cannot begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification to MEDIMMUNE. Written approval to proceed from the USAMRMC ORP is also required for any Subcontractor that will use funds from this Agreement to conduct research involving human subjects.

Subcontractor agrees to cooperate with any site visits conducted by MEDIMMUNE or the USAMRMC ORP for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the MEDIMMUNE and/or USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.
The Subcontractor is required to adhere to the following reporting requirements:
Submission of substantive modifications to the protocol, continuing review documentation, and the final report as outlined in this Agreement.

Unanticipated problems involving risks to subjects or others, subject deaths related to participation in the research, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, must be promptly reported to MEDIMMUNE.
Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to MEDIMMUNE.
The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies, and any instances of serious or continuing noncompliance with regulatory requirements that relate to this clinical investigation or research, must be reported immediately to the MEDIMMUNE.

Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the Agreement.

DoD requirements for human subjects research, including 32 CFR Part 219, DoD Instruction 3216.02, and USAMRMC ORP Human Research Protection Office submission instructions can be accessed at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

Prohibition of Use of Human Cadavers (NOVEMBER 2015)

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under this Agreement shall not begin until approval is granted by MEDIMMUNE, in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview).

The USAMRMC Office of Research Protections (ORP) is the Action Office for this policy. Approval must be obtained from MEDIMMUNE, who subsequently will obtain approval from the USAMRMC ORP. Written approval to proceed from the USAMRMC ORP is also required for any Subcontractor that will use funds from this Agreement to conduct RDT&E, education or training involving human cadaveric specimens.

Subcontractor must promptly report problems related to the conduct of the activity involving cadavers or the procurement, inventory, use, storage, transfer, transportation, and disposition of cadavers to the USAMRMC ORP through MEDIMMUNE.
Subcontractor must maintain complete records of the activity.
The USAMRMC or designees must be permitted to observe the activity upon request and/or audit activity records to ensure compliance with the approved protocol or applicable regulatory requirements.
Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the Agreement.

Administrative Requirements Incorporated by Reference (NOVEMBER 2015)
You are required to comply with any applicable terms and conditions for Subcontractors under the "Administrative Requirements for Grants and Awards with For-Profit Organizations" of the DoDGARs, located at 32 CFR part 34, incorporated herein by reference. The DoDGARs is available in full text at http://www.gpo.gov/fdsys/pkg/CFR-2011-title32-vol1/xml/CFR-2011-title32-vol1-subtitleA-chapI-subchapC.xml.

Prohibition on Using Funds under Grants and Cooperative Agreements with Entities that Require Certain Internal Confidentiality Agreements (NOVEMBER 2015)

a. The Subcontractor may not require its employees, contractors, or lower level Subcontractors seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting them from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

b. The Subcontractor must notify its employees, contractors, or Subcontractors that the prohibitions and restrictions of any internal confidentiality agreements inconsistent with paragraph (a) of this Agreement provision are no longer in effect.

c. The prohibition in paragraph (a) of this Agreement provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d. If MEDIMMUNE determines that the Subcontractor is not in compliance with this Agreement provision, it:

(1) Will prohibit the Subcontractor use of funds under this Agreement, in accordance with section 743 of Division E of the Consolidated and Further Continuing Resolution Appropriations Act, 2015, (Pub. L. 113-235) or any successor provision of law; and

(2) May pursue other remedies available for the Subcontractor's material failure to comply with Agreement terms and conditions.

ACKNOWLEDGED BY:

_____
Company Name

_____
Authorized Representative Signature

_____
Title

_____
Date

_____
E-mail