RESEARCH AND DEVELOPMENT SERVICES ADDENDUM
TO
PURCHASE ORDER TERMS AND CONDITIONS

This Research and Development Services Addendum supplements the Purchase Order Terms and Conditions to which this is attached.

1. DEFINITIONS.
"Audit For Cause" refers to any audit resulting from the following: (i) suspected or actual serious or persistent non-compliance with the Protocol, Provider's policies and procedures, this Order or any other Study-specific guidance; (ii) suspected or actual failure to perform any of the services set forth in this Order; and (iii) suspected or actual fabrication, falsification, plagiarism, deceptions or other practices that materially deviate from those that are commonly accepted within the scientific community for conducting or reporting clinical research, but not including honest error.
"CFR" refers to the United States Code of Federal Regulations.
"FDA" refers to the United States Food and Drug Administration.
"GLP Standards" refers collectively to Good Laboratory Practice regulations as set forth in Title 21, Part 58 of the CFR and all applicable guidelines; the Organizations for Economic Cooperation and Development Principles of Good Laboratory Practice and all applicable guidelines; and the Japanese Ministry of Health, Labor and Welfare Good Laboratory Practice Standards and all applicable guidelines.
"Human Substances" means cells, tissues, blood and other bodily fluids collected from human subjects, as well as any derivatives of any thereof, including but not limited to cell cultures, cell lines, expression vectors, and the like.
"Protocol" means the protocol, including any amendments thereto, governing the Study.
"Quality Agreement" means the Quality Agreement between Provider and Company, if any, that defines and establishes the quality assurance and quality control responsibilities of Provider.
"Records" refers to records, files, books, accounts, laboratory notebooks, and other documents and sources of information related to the services provided pursuant to this Order, including but not limited to records related to standard operating procedures, system validation, time expended, tests performed, and materials procured by Provider in performing the services.
"Study" means the study or research project to which the services hereunder relate.
"Study Materials" refers to biological specimens, original data, records, documentation, protocols and other such information and materials arising out of or in support of the Study.

2. ADDITIONAL REGULATORY REQUIREMENTS. Provider will provide services in compliance with GLP Standards unless explicitly provided otherwise in writing by the Company.

3. PROTOCOL AND AMENDMENTS TO PROTOCOL. Provider and the Company shall consult and mutually agree upon the Protocol. The Protocol, as amended from time to time, shall be deemed to be part of this Order and is incorporated herein by reference. Except for the purpose of complying with Applicable Laws, Provider shall not deviate from the Protocol without the prior written approval of the Company.

4. INFORMATION SYSTEMS. To the extent Provider creates, uses or modifies software or information systems in connection with providing the services, Provider represents and warrants that all such software or information systems (i) shall be maintained in a fully validated state and (ii) comply with, through electronic and/or manual controls (e.g., paper copies, personnel access controls), the standards contained in all Applicable Laws governing software or information systems relating to the conduct of clinical trials, including but not limited to Title 21 of the CFR, Part 11 (electronic document and data management). Provider shall notify Company thirty (30) days before making any changes or version updates to any electronic system used in the performance of the services and during the course of the services.

5. AUDITS. Unless otherwise provided for in the Quality Agreement, the following shall apply to Company audit of Provider facilities:
(a) Quality Audits. Provider shall, during the course of this Order and for a period of five (5) years after final payment from Company hereunder, maintain complete and accurate Records. Company and its representatives may, upon request, but no more than once every six (6) months, during normal business hours and after reasonable advance notice by Company, inspect Provider's facilities for quality assurance purposes, and inspect, copy, and audit the Records.
(b) Cause Audits. In addition to the audit rights above, Company and its representatives shall have the right, during normal business hours of operation and on reasonable prior notice to Provider, to inspect or audit Provider's facilities in an Audit For Cause. Such inspections or audits shall, to the extent reasonably practicable, be conducted in a manner that does not interrupt or impair in any significant manner the operations of such facilities.
(c) Audit Findings. At Company's or Provider's request, an exit meeting shall be held to discuss Company's audit findings. Company shall provide Provider with a written report summarizing its findings. Provider shall provide Company with a written response to such report within the time frame requested by Company. Such response shall include a plan for corrective and preventative actions designed to address reasonable concerns and shortcomings documented in Company's audit report. At no additional cost to Company, and without waiving any other rights or remedies that Company may have, Provider shall promptly remedy any audit findings by Company which relate to Provider's compliance with this Order.

6. COMMUNICATION AND COOPERATION WITH GOVERNMENTAL AUTHORITIES. Provider shall provide Company with all cooperation and assistance reasonably required by Company in connection with informal presentations, administrative hearings or court proceedings involving any governmental authority, and in private party litigation, to the extent such may be related to the services provided hereunder.

Provider shall disclose to Company all service-specific and service-impacting citations and observations (with redacted client confidential information) resulting from a governmental authority inspection of Provider's facilities. Notwithstanding anything contained in this Order to the contrary, Provider shall not initiate or participate in any communications with a governmental authority concerning the subject matter hereof unless required by law or requested to do so by Company and, then, only upon prior consultation with Company.

7. COMPANY LEGAL AND REGULATORY REVIEW. For any materials produced by Provider in performing the services that are intended to be made available to the public, prior to making any such materials available to the public, Provider must receive the approval of Company's law department. Provider shall make no changes to the materials as approved by Company.

8. STUDY MATERIALS. Provider shall retain in its archive for the period specified in the Protocol and as required by Applicable Laws all Study Materials. At the end of such archive period, Provider shall contact the Company for instructions on the transfer, retention or disposal of Study Materials. Shipping and handling costs for the transfer of the Study Materials to the Company, or fees mutually agreed to by the parties, in writing, for the continued retention of the Study Materials by Provider, will be invoiced to the Company. The Company's authorized representatives shall have the right to inspect the Study Materials at any time during the Study, and thereafter, while in the possession of Provider. Provider shall supply copies or samples, as the case may be, of the Study Materials to the Company, at any time and at the Company's request and expense, which shall not exceed Provider's established charges for such services at the time of request.

9. HUMAN SUBSTANCES. To the extent that the Study involves the collection, storage, and/or transfer of Human Substances, (i) the parties agree that the term "Applicable Laws", as used in this Order, includes all laws concerning the collection, storage, and transfer of Human Substances, regardless of the source of such Human Substances; and (ii) the party collecting and/or transferring the Human Substances represents and warrants that it has obtained

patient consent in writing permitting use of all Human Substances in the Study, and such patient consent imposes no restrictions of any kind on the collection, storage, transfer and/or use of the Human Substances for purposes of the Study.

10. USE OF ANIMALS IN RESEARCH. To the extent that the Study involves the use of animals in research, the parties agree that the term “Applicable Laws”, as used in this Order, includes all laws concerning the use of animals in research, including, but not limited to, the International Guiding Principles of Biomedical Research Involving Animals, the United States Department of Agriculture’s Animal Welfare Regulations and all current pertinent governmental regulatory requirements concerning animal welfare,