

MASTER SERVICES AGREEMENT

This Master Services Agreement (the “**Agreement**”) is entered into as of the date of last signature (the “**Effective Date**”) by and between **WIRB – COPERNICUS GROUP, INC.**, a Delaware corporation with its principal place of business located at 212 Carnegie Center, Suite 301, Princeton, NJ 08540, on behalf of itself and its Affiliates (collectively “**WCG**”) and the University of Southern California located at 3720 South Flower Street, Los Angeles, CA 90089-0702 (“**Client**”). Each of Client and WCG is referred to individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, WCG through its Affiliates, provides a range of clinical trial support services including but not limited to, compliance, consulting, technology, central rating and certification, site augmentation, patient recruitment and retention services, safety services, contract negotiation, budget development, education and training; and

WHEREAS, Client and WCG desire to enter into this Agreement to provide the terms and conditions upon which Client may engage the Services of WCG from time to time as may be described in one or more schedules (each a “**Schedule**”) as attached hereto and/or work order(s) (each a “**Work Order**”) attached hereto or incorporated herein specifying the details of the Services and the related terms and conditions.

NOW THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions.

- (a) “**Affiliate(s)**” shall mean with respect to WCG, any person or entity directly or indirectly controlled by or under common control with WCG, and shall mean with respect to Client, any person or entity directly or indirectly controlling, controlled by, or under common control with Client, and for this purpose, “control,” “controlling” and “controlled by” shall mean the ownership and control of more than fifty percent (50%) of the outstanding voting securities or interest in capital or profits of any person or entity by contract or similar arrangement.
- (b) “**Applicable Law**” means the federal and state laws and regulations applicable to such Services.
- (c) “**Confidential Information**” means any non-public, proprietary and confidential information that a Party may receive during the term hereof (the “**Receiving Party**”) from or on behalf of the other Party (the “**Disclosing Party**”), but does not include (i) aggregated or other information that cannot be attributed to the information of the Disclosing Party, or (ii) derivative information. Confidential Information, includes, without limitation, information about the Disclosing Party, and/or any of Disclosing Party’s customers including their respective business, products and services, including data, concepts, technical data, know-how,

research, plans, proposals, pricing or fees, software, source code, object code, developments, inventions, processes, designs, drawings, standard operating processes, legal and regulatory affairs, hardware or software configuration information, employees, and marketing, technical, strategic and/or financial information whether conveyed in writing, orally, by visual presentation, or via computer media but excludes all usage data related to the Services. WCG acknowledges that, as between WCG and Client, any “protected health information” (“**PHI**”) (as such term is defined in 45 C.F.R. Parts 160 and 164 under the Health Insurance Portability and Accountability Act of 1996, as amended from time to time (“**HIPAA**”), is Client Confidential Information. Confidential Information also includes information which, by its nature, should reasonably be considered to be proprietary or confidential information.

- (d) “**Study**” means a clinical trial with which Client is associated and for which WCG is providing Services.

2. Services.

- (a) Services and License to be Provided by WCG. WCG hereby agrees to provide to Client the services and/or license set forth in each Work Order executed by the Parties, substantially in the form of **Exhibit A** hereto, and/or the Schedules attached hereto (the “**Services**”). Any such Work Order will be executed by the Parties and is incorporated into and governed by this Agreement. If any term in a Work Order conflicts with this Agreement, this Agreement will control except to the extent that the applicable Work Order expressly states that such conflicting term prevails over this Agreement. Unless otherwise identified in a Work Order, any estimates of time or delivery date provided in connection with deliverables or Services, are good faith projections, but are not guarantees.

3. Compensation and Payment.

- (a) Compensation for Services is set forth in the applicable Work Order or Schedule.

4. Term and Termination.

- (a) This Agreement will commence on the Effective Date and will terminate on the fifth anniversary of the Effective Date unless earlier terminated in accordance with this Agreement. The term of each Work Order, as well as any renewal provisions applicable to such Work Order, shall be as specified in such Work Order. In the event the Agreement is terminated or expires, the terms and conditions of this Agreement shall continue in full force and effect, and shall continue to apply, with respect to all of the Work Orders then-in-effect for the respective Work Order terms.
- (b) Either Party may immediately terminate this Agreement and/or any individual Work Order(s), and/or WCG may suspend performance of Services, for a material breach of this Agreement or the applicable Work Order(s) by the other Party (the “**Breaching Party**”), provided that the Breaching Party fails to cure such material

breach within thirty (30) days after receipt of written notice specifying such material breach.

- (c) Either Party may immediately terminate this Agreement or any Work Order upon written notice to the other Party upon the happening of any of the following events: (i) if continuation of the Services would pose an undue risk to the health and/or wellbeing of a Study participant, (ii) if any certificate, authorization, approval or exemption from a regulatory authority required for the conduct of the Services is revoked, suspended, or expires without renewal, (iii) if such Party is of the reasonable opinion that the continuation of the Services would be in violation of Applicable Law, or (iv) upon the other Party's becoming insolvent and/or unable to pay all material debts when due, including without limitation if the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent.
- (d) Either Party may terminate this Agreement without cause upon one hundred and twenty (120) days' prior written notice to the other Party.
- (e) Termination of this Agreement or of a Work Order for any reason shall not affect the rights of the Parties that have accrued on or before termination.
- (f) Provisions Surviving Termination. The obligations of the Parties contained in Sections 1, 3, 4(e) and 4(f), 5, 6, 7(c), 8, 9, and 10 hereof (as well as any other provision that, in order to give proper effect to the surviving provisions, should survive such expiration or termination) shall survive termination of this Agreement.

5. **Confidentiality.**

- (a) **Confidential Information.** All Confidential Information, as defined herein, that is provided by Client to WCG relating to a Study or a potential Study, shall, in each case, be deemed to be "**Client Confidential Information.**" All Confidential Information pertaining to (i) WCG's Software, proposals, pricing, employees or contractors, and quotations (except to the extent that such information incorporates Client Confidential Information), methods, processes, know-how and standard operating procedures that are disclosed to Client, or (ii) all information that is or has been previously independently developed or collected by WCG without the benefit of any Client Confidential Information, including WCG Property, as defined in Section 6(b), shall be deemed to be "**WCG Confidential Information**" under this Agreement. Client Confidential Information and WCG Confidential Information may be referred to herein individually and collectively as Confidential Information. For purposes of this Agreement, each Party is the "**Disclosing Party**" with respect to its own Confidential Information, and a "**Receiving Party**" with respect to the Confidential Information of the other Party.

- (b) Use and Non-Disclosure of Confidential Information. The Receiving Party shall: (i) not disclose the Disclosing Party's Confidential Information to any third party without first obtaining the written consent of the Disclosing Party except as provided in this Section 5; and (ii) protect the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care used to protect its own confidential and/or proprietary information from unauthorized disclosure, but in no event with less than reasonable care. The Receiving Party will be permitted to furnish and otherwise disclose the Disclosing Party's Confidential Information to its Affiliates and those of its and their officers, directors, agents, contractors, subcontractors and consultants (collectively, "**Representatives**") and others who need to know such Confidential Information in order to accomplish the purposes of this Agreement, provided that such Representatives are bound by obligations of confidentiality with respect to such Confidential Information substantially similar to those provided herein. The Receiving Party shall be responsible for the actions and omissions of its Representatives as if they had been committed by Receiving Party.
- (c) Exceptions to Confidential Information. The obligations of confidentiality set forth in Section 5(b) shall not apply to any of the Disclosing Party's Confidential Information which the Receiving Party is able to demonstrate by competent proof:
- (i) was already known to the Receiving Party, without restriction, at the time of disclosure by the Disclosing Party;
 - (ii) was generally available to the public or otherwise part of or available to the public domain at the time of its disclosure to the Receiving Party;
 - (iii) later became part of the public domain through no act or omission of the Receiving Party;
 - (iv) was disclosed to the Receiving Party without obligations of confidentiality with respect thereto, by a third party who was not legally or contractually restricted from disclosing such information; or
 - (v) was independently developed by or on behalf of the Receiving Party without use of or reference to the Disclosing Party's Confidential Information.
- (d) Disclosure Required by Law. The Receiving Party may disclose the Disclosing Party's Confidential Information without violating the obligations of this Agreement to the extent that such disclosure is required by a valid order of a court, administrative agency, or other governmental body having jurisdiction, provided that to the extent practicable and permitted by Applicable Law, the Receiving Party provides the Disclosing Party with reasonable prior written notice of such court order or requirement to enable the Disclosing Party to seek a protective order or

other appropriate remedy preventing or limiting such disclosure when possible and makes a reasonable effort to assist the Disclosing Party in regard thereto.

- (e) Return of Confidential Information. Upon completion of the Services, termination of this Agreement or at the Disclosing Party's earlier written request, the Receiving Party shall return all Confidential Information provided by the Disclosing Party in documentary form, or, at the Disclosing Party's request, destroy all or such parts of the Disclosing Party's Confidential Information as the Disclosing Party shall direct, including any copies thereof made by the Receiving Party. Notwithstanding the foregoing, the Receiving Party may retain one hard copy of the Disclosing Party's Confidential Information solely for archival purposes, to satisfy regulatory and audit requirements or Confidential Information produced in the normal course of creating electronic back-ups of computer system information, which such Confidential Information shall remain subject to all the protections set forth herein.
- (f) Remedy. Each Party acknowledges that improper disclosure or distribution of the Disclosing Party's Confidential Information may cause irreparable harm for which damages at law may not be an adequate remedy. Accordingly, the Disclosing Party hereunder may seek to enforce the provisions of this Agreement prohibiting disclosure or distribution of its Confidential Information or use thereof contrary to the provisions hereof in a forum of competent jurisdiction, in addition to any and all other remedies available at law or in equity.
- (g) Privacy Laws. Each Party agrees that it will handle all information containing personal data in accordance with all governing privacy laws, including, to the extent applicable, United States state and federal law including, without limitation, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and the EU General Data Protection Regulation (2016/679) (the "**Regulation**") as it relates to the protection of the personal information of EU subjects, rules and regulations applicable to such personal data. WCG agrees to hold patient-identifiable information in confidence and to limit its use and/or disclosure of patient-identifiable information that it may obtain in the course of providing Services to the uses permitted under the applicable authorization and/or informed consent obtained from Study subjects, or as otherwise required by law.

6. Intellectual Property.

- (a) No License. Each Party agrees that neither Party transfers to the other Party by operation of this Agreement any patent right, copyright right, trademark right or other intellectual property right of such Party, except as may be specifically provided in this Agreement or any Work Order entered into hereunder.
- (b) Each Party's Property. A Party's "**Property**" means work papers, proprietary information, processes, methodologies, know-how, software, inventions, technology, trade secrets, improvements, and other assets (including, without limitation, those related to data collection processes, data management processes, analytical methods, procedures and techniques, computer technical expertise,

agreement templates and software (including codes)) that have been independently developed by such Party without the benefit of or access to any Confidential Information of the other Party and that do not relate to the composition of matter, formulation, or method of using, making or administering the drug that is the subject of any Study under a Work Order. A Party's Property is the sole and exclusive property of such Party and is that Party's Confidential Information.

7. **Representations and Warranties.**

- (a) **Due Authorization.** The persons executing this Agreement represent and warrant that they have the full power and authority to enter into this Agreement on behalf of each respective Party.
- (b) **No Debarred Person.** Each Party represents and warrants that it and its Affiliates are not presently debarred by the FDA pursuant to 21 U.S.C. § 335a or any similar non-United States law or regulations ("**Debarred**"). WCG agrees that it shall not knowingly employ, contract with, or retain any person or entity directly or indirectly to perform the Services if such a person or entity is Debarred or is, to its knowledge, under investigation by the FDA for Debarment. In addition, each Party represents and warrants that, to the best of its knowledge, it has not engaged in any conduct or activity which could lead to debarment actions. If, during the term of this Agreement, WCG, any of its Affiliates, or any person or entity employed or retained by WCG to perform the Services (i) to its knowledge comes under investigation by the FDA or any non-United States regulatory authority for Debarment, or (ii) is Debarred, WCG shall in each case promptly notify Client of same.
- (c) **Disclaimer of Warranties.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, TITLE OR FITNESS FOR A PARTICULAR PURPOSE. CLIENT AGREES THAT WCG MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE RESULTS OF THE SERVICES, INCLUDING BUT NOT LIMITED TO THE DEVELOPMENT AND/OR APPROVAL OF ANY STUDY DRUG AND/OR STUDY DEVICE THAT IS THE SUBJECT OF A STUDY BY ANY REGULATORY AUTHORITY.
- (d) **Anti-Bribery.** Each Party warrants that it will not make any payment, either directly or indirectly, of any money or other consideration (hereinafter "**Payment**"), to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively "**Officials**") where such Payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act. In no event shall either Party make any Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions

or actions with respect to the subject matter of this Agreement or any other aspect of its business.

8. **Indemnification and Insurance.**

- (a) **Client Indemnity.** Client shall indemnify, defend and hold harmless WCG and its employees, Affiliates, directors, officers, and agents (collectively, the “**WCG Indemnitees**”) from and against any and all damages, liabilities, losses, costs and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorney’s fees, expert witness and court costs (collectively, “**Losses**”), incurred in connection with any claim, demand, action, or proceeding brought by a third party (each, a “**Claim**”) to the extent arising from (i) failure to comply with the Study protocol, or (ii) the negligence, gross negligence or intentional misconduct on the part of Client Indemnitees (as such term is defined in Section 8(b) below) in connection with this Agreement; provided however, that Client shall have no obligation of indemnity hereunder with respect to a Claim to the extent that such Claim arises from (x) the negligence or gross negligence, or intentional misconduct on the part of a WCG Indemnitee or WCG’s subcontractors, (y) a breach of any of WCG’s material obligations, representations or warranties under this Agreement, or (z) infringement of a third party’s intellectual property rights based on Client’s use of WCG Property strictly in accordance with the Agreement.
- (b) **WCG Indemnity.** WCG shall indemnify, defend, and hold harmless Client and its employees, Affiliates, directors, officers, and agents (collectively, the “**Client Indemnitees**”) from and against any and all third party Losses incurred in connection with any Claim to the extent arising from (i) the negligence, gross negligence or intentional misconduct on the part of any of the WCG Indemnitees or any of WCG’s subcontractors in connection with this Agreement, (ii) a material breach of any of WCG’s material obligations, representations or warranties under this Agreement, or (iii) infringement of a third party’s intellectual property rights based on Client’s use of WCG Property strictly in accordance with the Agreement or WCG’s use of software, libraries, processes, methods, or other techniques to perform Services; provided, however, that WCG shall have no obligation of indemnity hereunder with respect to any Claim to the extent that such Claim arises from (x) the negligence, gross negligence, or intentional misconduct on the part of Client or its contractors, or (y) a breach of any of Client’s material obligations under this Agreement.
- (c) **Indemnification Procedure.** Each Party’s agreement to indemnify, defend, and hold harmless the other Party and its respective indemnitees is conditioned upon the indemnified Party: (i) providing prompt written notice to the indemnifying Party of any Claim, demand, or action arising out of the indemnified activities after the indemnified Party has knowledge of such Claim, demand, or action; however, any failure on the part of an indemnified Party to notify the indemnifying Party of receipt of notice of a Claim shall only relieve the notified Party of its obligation to indemnify the notifying Party for such Claim under this Agreement to the extent that the notified Party has been prejudiced by the lack of timely and adequate

notice; (ii) permitting the indemnifying Party to assume full responsibility and authority to investigate, prepare for, settle, and defend against any such Claim, demand, or action provided that the indemnified Party shall not be required to admit fault or responsibility in connection with any settlement; (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such claim, demand, or action; and (iv) not compromising or settling such Claim, demand, or action without the indemnifying Party's written consent. Notwithstanding the foregoing, the indemnifying Party shall not enter into any settlement (other than monetary settlement) or take any action that admits liability on the part of the indemnified Party, without their express written consent, which consent shall not be unreasonably withheld, delayed or conditioned.

- (d) Insurance. WCG will ensure that the following insurances remain in effect for the entire duration of this Agreement:

Insurance Type (if required)	Corresponding Insurance Details
Workers' Compensation Insurance	Workers' Compensation with statutory limits in accordance with the requirements of the state the WCG employee resides in.. If Supplier is self-insured for Workers' Compensation, Supplier will maintain a certified copy of the "Certificate of Consent to Self-Insure" required by California Labor Code Section 3700 et seq. and comply with the regulations promulgated thereunder. Employers Liability in the amount of \$1,000,000 each accident and \$1,000,000 annual aggregate.
Comprehensive General Liability Insurance	Comprehensive General Liability coverage for death, bodily injury, and property damage, including products liability, with limits of no less than \$1,000,000 per occurrence and \$2,000,000 in annual aggregate. Must not exclude Sexual Molestation Liability coverage.
Automobile Liability Insurance	Automobile Liability coverage of \$1,000,000 each occurrence and \$1,000,000 in the annual aggregate, for all owned, non-owned, and hired vehicles.
Professional Liability Insurance (Errors and Omissions)	Professional Liability coverage in the amount of \$2,000,000 per occurrence and \$2,000,000 in the annual aggregate if WCG is licensed or certified, or if WCG's work product, judgment, planning, or design will be relied on by Client in a decision-making process within Client.
Umbrella Policy	Umbrella Policy in excess of the General Commercial Liability Policy and Auto Liability policy with a minimum limit of \$5,000,000 per occurrence and \$5,000,000 in the annual aggregate.
Crime Insurance Policy	Intentionally left blank

Such coverages shall be obtained from an insurer having a minimum A.M. Best rating of A-,VIII, authorized to do business in the State of California, or be provided by licensee's affiliated

captive insurance company, and Commercial General and Auto Liability coverage shall name Client and its trustees, officers and employees as additional insureds. .

If any of either Party's insurance policies are on a "claims-made" form, such Party is required to maintain such coverage for a minimum of three (3) years following the expiration or any termination of this Agreement.

Promptly following the Effective Date, and no more than annually, WCG shall deliver to Client a certificate of insurance evidencing WCG's compliance with all the insurance requirements set forth in this Section 8 in the form reasonably satisfactory to Client.

During the term, Client shall maintain liability insurance, which may be pursuant to a program of self-insurance, consistent with commercially reasonable industry practices and sufficient to cover its obligations hereunder.

9. Limitation of Liability.

- (a) IN NO EVENT WILL EITHER PARTY BE ENTITLED TO, NOR SHALL EITHER PARTY BE RESPONSIBLE TO THE OTHER PARTY FOR, IN CONTRACT, TORT OR ANY OTHER CAUSE OF ACTION, ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING LOST PROFITS) ARISING IN CONNECTION WITH A PARTY'S DEFAULT OR BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT.
- (b) EXCEPT FOR A PARTY'S INDEMNIFICATION OBLIGATION WITH RESPECT TO THIRD PARTY CLAIMS HEREUNDER, THE TOTAL LIABILITY OF THE PARTIES OR ANY AFFILIATE THEREOF IN CONNECTION WITH THIS AGREEMENT, A SCHEDULE, WORK ORDER, OR ANY STUDY (WHATEVER THE BASIS FOR THE CAUSE OF ACTION) SHALL NOT EXCEED TWO (2) TIMES THE FEES ACTUALLY PAID TO WCG OR ANY AFFILIATE THEREOF FOR THE SPECIFIC SERVICES GIVING RISE TO THE CAUSE OF ACTION WITHIN THE TWELVE (12) MONTHS PRIOR TO THE INCIDENT GIVING RISE TO THE CAUSE OF ACTION.

10. Miscellaneous.

- (a) Independent Contractor Relationship. The Parties hereto are independent contractors, and nothing contained in this Agreement is intended, and shall not be construed, to place the Parties in the relationship of partners, principal and agent, employer/employee or joint venture. Neither Party shall have any right, power or authority to bind or obligate the other, nor shall either hold itself out as having such right, power or authority.
- (b) Publicity. Except as required by valid order of a court or other governmental body having competent jurisdiction, or by Applicable Law, neither Party shall use the

name of the other Party or of any agent thereof for purposes of publicizing this Agreement or any Study performed hereunder without the prior written consent of the other Party. The Parties agree to issue a jointly approved press release upon execution of this Agreement.

- (c) Force Majeure. If either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, terrorism, epidemic, pandemic, war, acts of God, inclement weather, fire, earthquake, or other reason or cause reasonably beyond such Party's control (each a "**Force Majeure**"), then performance of such act shall be excused for the period of such Force Majeure. Any timelines affected by a Force Majeure shall be extended for a period equal to that of the Force Majeure. The Party incurring the Force Majeure shall provide notice to the other of the commencement and termination of the Force Majeure, and shall take reasonable, diligent efforts to remove the condition constituting such Force Majeure or to avoid its affects so as to resume performance as soon as practicable.
- (d) Delays. WCG's performance under this Agreement or any Work Order may be contingent upon the performance of obligations by another party, including, but not limited to, Client itself, Client-designated vendors, Client's customers and other third parties. To the extent that WCG is delayed or unable to perform its obligations under this Agreement or any Work Order as a result of Client's failure to perform its obligations, in a timely manner or otherwise, such delay or failure to perform by WCG will not be deemed a breach by WCG.
- (e) Notices. Any notice or communication required or permitted hereunder, will be in writing and sent by first class mail, or postage prepaid, to the Parties at the following addresses:

To WCG:
WIRB – Copernicus Group, Inc.
212 Carnegie Center, Suite 301
Princeton, NJ 08540
ATTN: Legal Department

To Client:
University of Southern California
3720 South Flower Street
Los Angeles, CA 90089-0702
ATTN: Interim Director

With a copy to:
University of Southern California
1510 San Pablo St.
Los Angeles, CA 90033
Attn: Associate General Counsel

- (f) Severability. If any term of this Agreement is declared unenforceable, then the unenforceability thereof will not affect the remaining terms of this Agreement.
- (g) Waiver. Waiver or forbearance by either Party hereto of any of its rights under this Agreement or Applicable Law in any one or more instances must be in writing and

signed by the waiving Party and shall not be deemed to constitute a waiver or forbearance of any other right or a further or continuing waiver of such rights.

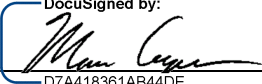
- (h) Assignment. Either Party may assign, with prior consent from the other Party, this Agreement to an Affiliate or a successor in interest by reason of merger, acquisition, partnership, license agreement or otherwise; provided that no assignment to a direct competitor of the other Party will be valid and further provided that the assigning Party, if it survives, shall remain liable for all obligations under this Agreement. Except as expressly provided in this Section, neither Party will have the right to assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed. Any assignment in violation of this Section shall be null and void.
- (i) Governing Law and Dispute Resolution. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, USA. This Agreement has been entered into in the English language, which language shall govern the interpretation of this Agreement. All disputes arising under or in connection with this Agreement shall be submitted to JAMS or successor organization for binding arbitration by a single arbitrator. The arbitrator shall be selected by JAMS in an impartial manner determined by it. The arbitration hearing will be commenced within one hundred eighty (180) days of the filing of an arbitration demand with JAMS by any Party hereto, and a decision shall be rendered by the arbitrator within thirty (30) days of the conclusion of the hearing. The arbitrator shall have complete authority to render any and all relief, legal and equitable, appropriate under this Agreement. The arbitrator shall award costs of the proceeding, including reasonable attorney's fees, to the Party determined to have substantially prevailed.
- (j) Counterparts. This Agreement, and any subsequent amendment(s), may be executed in counterparts, by electronic, scanned or other acceptable signature, and the counterparts, together, shall constitute a single agreement.
- (k) Non-Solicitation. Each Party agrees, on behalf of itself and its Affiliates, not to directly or indirectly solicit for employment, employ or otherwise retain staff of the other Party who have been materially involved with a Study governed by this Agreement or Work Order hereunder during the term of this Agreement and for a period of twelve (12) months following any termination or expiration of this Agreement or the applicable Work Order; provided that neither party is prohibited from (i) soliciting employment by placement of general advertisements for employees on any internet site, in newspapers, or via other media of general circulation not specifically directed at the employees of the other Party; (ii) soliciting persons identified through employment search firms that are not specifically directed at the employees of the other Party; or (iii) soliciting or hiring any person who contacts the hiring Party on his or her own initiative without any prior solicitation or recruitment (other than advertisements of the type contemplated by the preceding clauses).

- (l) No Third Party Beneficiaries. This Agreement shall not confer upon any person, other than the Parties, any rights or remedies with respect to the subject matter hereof.
- (m) Entire Agreement. This Agreement constitutes the entire agreement between the Parties concerning its subject matter and supersedes all other prior oral or written understandings and agreements between the Parties.

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives effective as of the Effective Date.

WIRB – COPERNICUS GROUP, INC.

UNIVERSITY OF SOUTHERN CALIFORNIA

By: 
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By: 
Ishwar K. Puri (Oct 8, 2021 13:46 PDT)

Name: Marco Capasso

Name: Ishwar K. Puri

Title: General Counsel

Title: Vice President of Research

Date: 11-Oct-2021 | 8:47 AM PDT

Date: Oct 8, 2021

SCHEDULE A

IRB SERVICES

1. IRB Services. The Services performed by WCG under this Schedule are institutional review board (“**IRB**”) Services.
 - 1.1 Client requests WCG serve as an IRB of record for Studies submitted to WCG.
 - 1.2 WCG agrees to serve as an IRB of record for Client’s Studies, provided that nothing herein will be construed to limit WCG’s independence to take actions necessary to protect the subjects’ rights and welfare, or to alter WCG’s primary duty to the subjects under Applicable Law.
 - 1.3 Scope.
 - (a) Client shall use WCG as an independent IRB for studies submitted to WCG.
 - 1.4 Transfer of Existing Studies.
 - (a) With regards to any industry-sponsored Study currently being conducted at a Client Site (as defined in Section 8.3 below), whether being reviewed by Client’s local IRB or by another central IRB, the Client has the option of transferring these Studies to WCG (collectively, the “**Transferring Studies**”).
 - (b) The Parties shall establish a reasonable process pursuant to a transfer agreement signed by both Parties to ensure that all of these Transferring Studies are transferred properly and expeditiously, including, without limitation, co-drafting the communication that will be sent to each such Sponsor of such Transferring Studies, and sending out such communication.
 - 1.5 Provider of IRB Services.
 - (a) With respect to any Study that is submitted to WCG hereunder, the submission form used shall identify the WCG Affiliate to whom such Study is submitted, unless the Parties mutually agree to another mechanism, and both Parties hereby acknowledge and agree that it is such WCG Affiliate that shall be the IRB of record for Client, and the provider of IRB Services, for such Study.
2. WCG Responsibilities.
 - 2.1 IRB Services. WCG and its Representatives will act as an IRB, performing all tasks and responsibilities required by Applicable Law, including doing the following:
 - (a) Conduct an initial review of each Study.
 - (b) Review all subject information and consent documents.
 - (c) Review Site-specific materials, including a completed Site-specific submission form.
 - (d) Provide continuous oversight of each Study it approves.
 - (e) Consistent with 21 C.F.R. § 56.109(f), and as WCG may determine reasonably necessary, Client shall cause each Site to permit site visits by WCG during business hours, with reasonable advance notice, at a mutually agreeable time. A site visit may involve meeting with the Principal Investigator and Site staff, and may include review of the following: the conditions surrounding the conduct of the Study, the Study records, the attitudes of the community from which Study subjects are selected, the current status of the Study, the consent process, subject complaints, unusual reports, unanticipated problems, high drop-out rates, or any other factor that WCG reasonably considers relevant to the conduct of Study.
 - (f) Conduct continuing review of each approved Study at intervals appropriate to the degree of risk in such Study, but not less than once per year.
 - 2.2 Notifications.
 - (a) WCG shall send timely notices to the FDA or OHRP as required by Applicable Law, such as (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with FDA or HHS regulations, as applicable, or the requirements or determinations of WCG; and (iii) any suspension or termination of IRB approval.
 - (b) WCG shall promptly notify the Principal Investigator, USC IRB, and the applicable institution of any of the following WCG actions relative to a Study:
 - (i) Termination or suspension;

- (ii) Serious or continuing noncompliance with the federal regulations or the requirements and determinations of WCG;
 - (iii) Approval, disapproval, or recommendation to modify; and
 - (iv) Copies of any reports that WCG sends pursuant to Section 2.2(a).
 - 2.3 Knowledge of the Local Research Context. Pursuant to Applicable Law, WCG shall take such actions as are necessary to ensure knowledge of the local research context, including on-site visits, videoconference or teleconference meetings as WCG may deem appropriate, and Client shall provide all such assistance in connection therewith as WCG may reasonably request.
 - 2.4 Debarment. WCG shall not employ any person directly or indirectly to perform any IRB Services if such person is debarred by the FDA under 21 U.S.C. 335a.
 - 2.5 Site Selection Enhancement Services. WCG will provide to Client its site selection enhancement Services whereby WCG works with Sponsors, CROs and other entities in an effort to attract more Studies to Client. To that effect, (i) WCG may seek information about Client to assist in such effort, including with respect to Client's study history and principal investigators, and (ii) WCG, in its reasonable discretion, may provide such data with such entities.
- 3. Client Responsibilities.
 - 3.1 Client shall ensure its Principal Investigators are qualified by training and experience as appropriate experts to conduct the Studies. Client will advise the Principal Investigators, CROs, appropriate federal agencies, or other relevant parties, as applicable, that WCG is the IRB of record for the applicable Studies.
 - 3.2 Client shall promptly communicate or provide, and/or where necessary and applicable, cause each Principal Investigator or Site staff to promptly communicate or provide a completed submission form and any other information required by WCG's standard submission requirements, including the following, to WCG in a timely manner:
 - (a) All the materials required to be provided pursuant to WCG's standard submission process.
 - (b) Any and all amendments to the Study or modifications to the human subjects research.
 - (c) Any documents or information required for WCG to conduct continuing review.
 - (d) Any unanticipated problems that may increase risk to subjects or others including problems that arise during a Study that involve risk to the research subjects or others and are (a) unexpected, (b) involve serious harm or a potential for serious harm to a research subject or other person, and (c) that are more likely related than unrelated to participation in the Study.
 - 3.3 Other Client Obligations.
 - (a) Nothing in this Agreement will be construed to override or change Client's duties under Applicable Law.
 - (b) In keeping with the requirements of 21 CFR § 56.112, Client cannot approve any research study that has been disapproved by WCG.
 - (c) Client agrees to abide by the decisions of WCG and shall use its best efforts to ensure that the research performed by the Client shall be conducted in accordance with those decisions.
- 4. Fees.
 - 4.1 IRB Services shall be performed pursuant to WCG's then-current applicable fee schedules (each an "IRB Fee Schedule"), which fee schedule(s) are subject to change in WCG's sole discretion. The IRB Fee Schedules in effect as of the date hereof have been provided under separate cover.
- 5. Term; Termination.
 - 5.1 The term of this Schedule shall be the same as for the Agreement. Notwithstanding the foregoing and at any time, Client may request closure of any Study.
 - 5.2 Notwithstanding the termination or expiration of the Agreement and/or this Schedule, such termination shall not affect WCG's obligations to provide IRB Services for any Study then under review, until such Study is properly closed and/or transferred to and re-reviewed by another responsible IRB, and WCG shall continue to earn fees until such time.
- 6. Access, Recordkeeping and Reporting.
 - 6.1 Access. It is agreed that Client or its authorized representative(s) may, during regular business hours and upon mutually agreeable terms, arrange with reasonable advance notice to WCG to:
 - (a) Inspect WCG's facilities required for performance of the IRB Services to be provided hereunder; and
 - (b) Examine applicable work product relating to the IRB Services to be provided hereunder;

provided that before any authorized representative is permitted such access, WCG may require that such representative execute a non-disclosure agreement, preapproved in writing by Client, for the benefit of WCG containing provisions substantially similar to those set forth in the Agreement.

- 6.2 Regulatory Audits. WCG agrees to cooperate with governmental authorities in connection with audits and inspections of WCG relative to Client's Studies.
- 6.3 Records/Retention. WCG shall generate and retain complete written records, documents, accounts, reports and data of the IRB Services performed hereunder in accordance with Applicable Law.
- 7. Notices. All notices shall be provided in accordance with the provisions set forth in the body of the Agreement.
- 8. Definitions. Capitalized terms used but not otherwise defined in this Schedule or the Agreement shall have the meanings ascribed to such terms in this Section 8. In addition, to the extent that the body of the Agreement or any other Schedule contains any terms that are defined in this Schedule, and such term is not also defined in the body of the Agreement or such other Schedule, the term shall have the meaning ascribed to it hereto.
 - 8.1 "**CRO**" means a contract research organization, as this term is defined by 21 C.F.R. § 312.3.
 - 8.2 "**Principal Investigator**" means an individual who actually conducts an investigation, i.e., under whose immediate direction the test article, if any, is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.
 - 8.3 "**Site**" means the location(s) where Human Subjects Research-related activities are actually carried out.
 - 8.4 "**Sponsor**" means the sponsor of any Study.

[end of Schedule A]

EXHIBIT A**SAMPLE
FORM OF WORK ORDER****Protocol No. [ENTER PROTOCOL NO.]**

This Work Order (this “**Work Order**”) is made and entered into as of the last date of signature below (the “**Work Order Effective Date**”) by and between [ENTER CLIENT FULL NAME] (“**Client**”) and [ENTER WCG ENTITY FULL NAME] (“**XXX**”) pursuant to and subject to the terms and provisions of that certain Master Services Agreement, dated as of [ENTER DATE], by and between **Client** and **XXX** (the “**Agreement**”). Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to them in the Agreement.

Client and **XXX** hereby agree as follows:

- 1. Purpose.** Client has agreed to engage WCG to provide certain services relating to Protocol No. [PROTOCOL NO.], entitled “[ENTER STUDY NAME]”, which has been previously provided to WCG (the “**Study**”), which services are more specifically described in Section 2.
- 2. Services.** WCG shall perform the services described in Attachment 1, Scope of Work, of this Work Order (the “**Services**”) in accordance with the terms of this Work Order and in accordance with the terms of the Agreement.
- 3. Payment.** In consideration of WCG’s performance of Services, Client, or its designee, shall pay WCG [SPELL OUT AMOUNT] US Dollars and Zero US Cents (\$[AMOUNT]), in accordance with the Agreement, and, where it does not conflict with the Agreement, in accordance with Attachment 2, Budget and Payment Schedule, attached hereto.

Client and WCG agree that the amount of compensation payable to WCG for the performance of the Services reflects the fair market value of the Services being performed by WCG hereunder. Client and WCG confirm that WCG has been selected to perform the Services because of WCG’s experience in the clinical research services industry and not, in any way, as an inducement to, or in return for, prescribing or causing to be prescribed, purchasing, using or recommending any product of Client or its Affiliates. Client and WCG agree that any payment provided under this Work Order is consistent with an arm’s length transaction for services of the kind provided hereunder, is not in exchange for any Agreement by WCG or any of its Affiliates, whether express or implied, to prescribe or cause to be prescribed, use or recommend the prescription or use of any product of Client or its Affiliates, and is not determined in a manner that takes account of the volume or value of any referrals or business otherwise generated between the Parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs as defined in 42 USC section 1320a-7b(f).

- 4. Term.** This Work Order shall begin on the Work Order Effective Date and shall continue until all Services herein have been completed, unless terminated earlier in accordance with the terms of the Agreement.

- 5. **Amendments.** No modification, amendment or waiver of this Work Order shall be effective unless in writing and signed by both Parties hereto.
- 6. **Conflicts.** To the extent any terms in this Work Order conflict with the terms of the Agreement, the terms of the Agreement shall govern, unless otherwise expressly provided in this Work Order.
- 7. **Counterparts.** This Work Order may be executed in multiple, identical counterparts, each of which shall be an original but all of which together shall constitute one and the same instrument. Signatures to this Work Order transmitted by electronic mail in “portable document format” (“.pdf”) form will have the same effect as physical delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, this Work Order has been executed and delivered by the Parties hereto as of the Work Order Effective Date.

[WCG AFFILIATE]

[CLIENT LEGAL NAME]

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Work Order Attachment 1

Scope of Work

Work Order Attachment 2

Budget and Payment Schedule

BUDGET

PAYMENT SCHEDULE






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Final Audit Report

2021-10-08

Created:	2021-10-07
By:	shontaib@usc.edu
Status:	Signed
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