Quorum

Institutional Start-Up Package

Your First Step to Working with Quorum Review IRB

February 2016

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Dear Colleague:

Patient protection in clinical trials is taking center stage in our industry, while at the same time, organizations are being asked to do more with less. IRBs within institutions are looking for ways that they can expand their current capacity and improve their review cycle timelines without increasing costs. Some institutions are looking for secondary supplier alternatives while others are looking to focus on research and outsource the IRB function all together.

Quorum Review IRB can help. Quorum Review is an AAHRPP accredited independent ethics review board that offers customized processes for the ethics review of institutional research.

Funding agencies and study sponsors are placing increasing emphasis on ethics review by an accredited board. Thought leaders recognize that independent review boards can provide high-quality oversight. The time has never been better to shift some or all of your institution's reviews to an independent ethics review board. Many institutions already outsource the review of studies regulated by the Food and Drug Administration, and the Office of Human Research Protections is contemplating legislation that would further encourage institutions to shift review functions to outside ethics review organizations.

And in a world in which budgets are shrinking, Quorum Review offers the efficiencies and reliability of one of the largest ethics review organizations in the nation.

The goal of this Institutional Start-Up Package is to make it easy for you and your institution to establish a relationship with Quorum Review. Once the relationship is established, we can work with your institution when you are ready - on a study-by-study basis or more globally on industry sponsored studies. Within this packet you will find a template contract, a guide to evaluating consent forms, and an example of a customized cover page for site submissions.

Please feel free to contact me if you have any additional questions or would like me to contact another individual within your organization to move the process along. Quorum is committed to our relationships with institutions.

Warm Regards,

Michael Quinn
Manager, Sales & Business Development
busdev@quorumreview.com
206-436-3215

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SETTING UP A RELATIONSHIP WITH QUORUM REVIEW IRB

There are several different steps that can occur when an institution establishes a working relationship with Quorum Review IRB. A menu of options is below as well as a description of each option. Should you require further assistance please contact Business Development, 206-448-4082 or busdev@quorumreview.com.

Options for establishing a working relationship

1. **Confidentiality/Disclosure Agreement (CDA)** - Protects the exchange of confidential information.
2. **Institutional Authorization Agreement (IAA)** – A brief agreement to establish the relationship between Quorum Review and the institution on a study-by-study basis.
3. **Master Jurisdiction Agreement (MJA)** – A more extensive version of the IAA to better define the terms of the relationship, including the deliverables to the institution, communications between the institution and Quorum, definitions of unique requirements, and establishing how the institution and Quorum will identify those studies subject to the agreement.
4. **Consent form template language** – Upon request, the Quorum Review IRB will review proposed template sections of a consent form and provide pre-approval for that language to be used.
5. **Training of institutional staff** – Quorum Review can train, at no charge, the institution's clinical staff on how best to work with Quorum.
6. **Site Visit of Institution** – Quorum Review prefers to conduct regular site visits of institutions.
7. **Site Visit of Quorum Review** – Quorum Review invites institutions to visit our office in downtown Seattle.

Explanations of options

1. Confidentiality/Disclosure Agreement

Purpose: This short contract serves as a legal means of compelling both sides to respect the confidentiality of our relationships.

Tools provided: Quorum has provided in this package a template CDA. Feel free to propose revisions or propose use of your organization's template.

Where to send the completed information: Please submit to Business Development by email at busdev@quorumreview.com. The document will be routed to Quorum's contract group for approval.

2. Institutional Authorization Agreement

Purpose: An institutional authorization agreement (IAA) spells out the relationship between the institution's IRB and Quorum Review IRB. Quorum accepts on a study-by-study basis the template IRB/IEC Authorization Agreement posted by the Office of Human Research Protection (OHRP) at http://www.hhs.gov/ohrp/assurances/. Alternatively, you can use Quorum's partially pre-populated version of the IAA (enclosed).

Tools provided: Quorum has provided in this package a partially pre-populated IAA. Feel free to propose revisions or propose use of your organization's template.

Where to send the completed information: Please submit to Business Development by email at busdev@quorumreview.com. The document will be routed to Quorum's contract group for approval.

1501 Fourth Avenue
Suite 800
Seattle, WA 98101
QuorumReview.com

D/ 206 448 4082
T/ 877 472 9883
F/ 206 448 4193

3. **Master Jurisdiction Agreement**

Purpose: A Master Jurisdiction Agreement (MJA) spells out the terms of the working relationship with Quorum Review IRB in more detail than an IAA and can apply to all studies submitted to Quorum. The following items can be addressed in the MJA:

- Template consent form language to be pre-approved by the Board;
- How institution researchers will submit to Quorum Review;
- Any unique requirements of the institution.

Tools provided: Quorum has provided in this package a template MJA. Feel free to propose revisions or propose use of your organization's template.

Where to send the completed information: Please submit to Business Development by email at busdev@quorumreview.com The document will be routed to Quorum's contract group for approval.

4. **Consent Form Template Language**

Purpose: The consent form negotiation part of study start-up can get very complicated. In order to streamline this process, the Quorum Review IRB can review and pre-approve sections of a template consent form prior to receiving a submission from the institution. This is especially helpful for institution-specific HIPAA language, emergency contact information, etc. Establishing this process prior to submission greatly alleviates many of the headaches of this process.

Tools provided: When you submit a draft MJA to Quorum Review, please include a generic consent form containing all the required elements for your institution. If you need assistance drafting your consent form language, Quorum has a variety of templates available as well as guidance to consent form development. Please contact Customer Relations at 206-448-4082 or CustomerRelations@quorumreview.com.

Where to send the completed information: Once your template consent form is complete please submit to Business Development at busdev@quorumreview.com.

5. **Training of Institution Staff**

Quorum understands that there is a learning curve with utilizing a new service. To that end, we are willing to provide training webinars at your convenience – or we could arrange a visit to your institution. If interested, please send an email to Business Development at busdev@quorumreview.com.

6. **Site Visit of Institution**

Quorum Review prefers to conduct site visits of institutions. A site visit probably will be requested within a year of signing an MJA.

7. **Site Visit of Quorum Review**

Quorum Review is located in the heart of downtown Seattle. We invite you to visit Quorum to get to know us better, meet our Board members and become comfortable with our policies and procedures.

1501 Fourth Avenue
Suite 800
Seattle, WA 98101
QuorumReview.com

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T/ 877 472 9883
F/ 206 448 4193

CONFIDENTIAL DISCLOSURE AGREEMENT

THIS CONFIDENTIAL DISCLOSURE AGREEMENT ("Agreement") is made and entered into as of the ____ day of_____, 20___ ("Effective Date"), by and between _____, a _____ corporation ("Customer") with offices located at _____, and Quorum Review, Inc. (d/b/a Quorum Review IRB), a Washington corporation ("Quorum") with offices at 1501 Fourth Avenue, Suite 800, Seattle, WA 98101-3658, and shall govern the disclosure between the parties of confidential and proprietary information. To ensure the protection of such information and in consideration of the agreement to exchange said information, the parties agree as follows:

1. Terms. The term "Confidential Information" shall mean any information that the receiving party ("Recipient") receives from or on behalf of the disclosing party ("Discloser") or which the Recipient derives therefrom, including any information, data or reports the Recipient may generate and including, without limitation, proprietary products, technology, literature, clinical or other research, regulatory data or plans, clinical data or plans, proposal plans, product plans, Board and consultant rosters, training materials, standard operating procedures, Board minutes, product candidates, pricing and fee structures and customer and vendor data and relationships associated with the products and services of the Discloser, whether disclosed in writing, orally, electronically, or by drawings. Further, any information learned through observation during visit(s) to the other party's facilities shall also be deemed Confidential Information subject to such obligations.

2. Confidentiality. Recipient agrees to maintain the confidentiality of Confidential Information and shall not disclose it to any third party without the prior written authorization from Discloser. Recipient shall exercise at least the same degree of care as it customarily takes to preserve and safeguard its own proprietary information, which in no event shall be less than a reasonable standard of care. Recipient has obtained or will obtain, prior to any disclosures hereunder, written agreements with its employees, contractors, and agents to maintain the confidentiality of such Confidential Information as is exchanged herein. Each party shall promptly advise the other in writing if either learns of any unauthorized duplication, use or disclosure of Confidential Information.

3. Exclusions. These obligations of non-disclosure shall not apply to Confidential Information that:

    a. Is already known to Recipient as shown by its prior written records;

    b. Is or becomes publicly available through no fault of Recipient and without use of or reference to Discloser's Confidential Information;

    c. Is received from a third party which has the legal right to disclose it to Recipient;

    d. Is independently developed by Recipient without use of or reference to Discloser's Confidential Information; or

    e. Is required by law, court order, subpoena, government order or other lawful request to be disclosed, provided that Discloser is notified, in writing, ten (10) days prior to such lawful disclosure if possible, or as soon as possible thereafter, and Recipient shall cooperate with the Discloser if the Discloser elects to contest and/or avoid such ordered disclosure or obtain confidential treatment of such disclosure. In any event, the Recipient shall disclose only that portion of the Confidential Information that, in the opinion of its legal counsel, is legally required to be disclosed and will exercise

reasonable efforts to ensure that any such information so disclosed will be accorded confidential treatment by the said court or tribunal.

4. Exclusive Ownership. All Confidential Information shall remain the exclusive property of the Discloser and shall be destroyed by the Recipient or returned by the Recipient to the Discloser promptly upon written request of the Discloser, together with all copies thereof, except the Recipient may retain one (1) archival copy as required by law or its written procedures. Upon the request of the Discloser, the Recipient shall destroy and certify to the Discloser the destruction of any and all documents, papers, electronic or other media and materials and notes thereon, including copies, summaries or reproductions thereof, that contain Confidential Information of the Discloser. The return and/or destruction of such Confidential Information shall not relieve the Recipient of its other obligations under this Agreement.

5. Term. The Recipient's obligations of confidentiality set forth in this Agreement shall terminate five (5) years after the Effective Date of this Agreement (the "Termination Date"), unless otherwise extended by mutual agreement of the parties. This Agreement shall be binding upon the Recipient, its affiliates, assignees, and successors for a period of five (5) years after the Termination Date, unless otherwise extended by mutual agreement of the parties, and shall inure to the benefit and be enforceable by the Discloser, its successors and assignees.

6. Parties. Each party's relationship with the other is and shall be that of an independent contractor, and no partnership, joint venture, co-venture, employer/employee, principal/agent, master/servant or other similar relationship is created, or intended to be created, hereby. Nothing in this Agreement shall obligate either party to disclose any Confidential Information and nothing in this Agreement shall require either party to engage in business with the other.

7. Notice. All notices relating to the terms of this Agreement shall be delivered personally, by registered or certified first class mail, or by overnight courier service to the contact addresses set forth below the signature lines at the end of this document. Notice shall be effective upon receipt if personally delivered upon the third business day following the date of mailing by registered or certified first class mail; or on the first business day following the date of delivery to the overnight courier. A party may change its address listed below by written notice to the other party.

8. Relief. The Recipient acknowledges and agrees that the Confidential Information has commercial and other value, is of a sensitive nature and that any unauthorized disclosure of any Confidential Information or other violation, or threatened violation, of this Agreement would cause irreparable damage to the Discloser, and that, therefore, the Discloser shall be entitled to seek, without limiting the remedies otherwise available to the Discloser, an injunction or other equitable relief prohibiting such disclosure, attempted disclosure or violation or threatened violation of this Agreement.

9. License. This Agreement shall not be construed as creating, conveying, transferring, granting or conferring upon either party any rights, license or authority in or to the information exchanged, except the limited right to use Confidential Information specified in the Purpose. Furthermore and specifically, no license or conveyance of any intellectual property rights is granted or implied by this Agreement.

10. Limitation of Liability. Neither party shall be liable to the other in any manner whatsoever for any decisions, obligations, costs or expenses incurred, changes in business practices,

plans, organization, products, services, or otherwise, based on either party's decision to use or rely on any information exchanged under this Agreement.

11. Miscellaneous.

A. Entire Agreement: Amendments. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and there are no agreements, relationships or undertakings with respect thereto or implied, other than as set forth herein. This Agreement may be amended from time to time upon the mutual written agreement of the parties hereto. If any provision of this Agreement is found by a proper authority to be unenforceable, that provision shall be severed and the remainder of this Agreement will continue in full force and effect.

B. Waiver of Breach. Neither the failure nor any delay on the part of either party to exercise any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or privilege preclude any other or further exercise thereof, or the exercise of any other right, power or privilege. In the event a party should waive any breach of any provision of this Agreement, it shall not be deemed or construed as a waiver of any other breach of the same or different provisions.

C. Governing Law. This Agreement shall be governed, construed, and enforced in accordance with the laws of the State of Washington, without regards to its conflict of laws rules. Any dispute arising under this Agreement shall be brought exclusively in the state and federal courts sitting in the State of Washington, and each party hereby submits to such exclusive jurisdiction.

D. Authority to Sign. The persons who sign the agreement on behalf of the Customer and Quorum are acting within the scope of their authority as agents.

IN WITNESS WHEREOF, the parties thereto have caused this Agreement to be duly executed as of the date set forth above.

[INSERT COMPANY NAME]		QUORUM REVIEW, INC.	
(Authorized Signature)		(Authorized Signature)	
Name:		Name:	
Title:		Title:	
Address:		Address:	1501 Fourth Ave
			Suite 800
			Seattle, WA 98101
Date:		Date:	

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MASTER JURISDICTION AGREEMENT

Instructions: All sections highlighted in yellow must be completed prior to contract execution

This agreement is dated [Date] and is between QUORUM REVIEW, INC. (d/b/a Quorum Review IRB), a Washington corporation ("**Quorum"**), with offices located at 1501 Fourth Avenue, Suite 800, Seattle, Washington 98101, and [**Institution Name**] a [State] [corporation/limited liability company] with its principal place of business located at [Address].

RECITALS

United States Federal law and regulations require the review services of an institutional review board (IRB) before conducting non-exempt research involving human subjects ("Studies").

Institution requires IRB review services ("Services") for Studies conducted at the Institution by Principal Investigators employed by, or otherwise affiliated with, the Institution ("Investigators").

Quorum maintains an IRB and provides IRB review services for Institutions.

The parties therefore agree as follows:

1. DESCRIPTION OF SERVICES

A. **Services.** Quorum will assume IRB oversight of Studies submitted by the Institution. Quorum will perform the Services described below in compliance with applicable laws, regulations, and guidelines and Quorum's procedures and policies. The Services provided by Quorum under this agreement shall include:

i. Review of Studies, including protocols, associated consent form(s), advertisements and other recruitment materials.

ii. Review of Investigators, including review of information about the Study staff and resources at the research site.

iii. Review of amendments to Study protocols, including amended consent forms or other changes.

iv. Review potential unanticipated problems involving risk to participants or others, including serious and unexpected adverse events, review of Investigational New Drug (IND) safety reports and other events that qualify for reporting to the IRB under Quorum's reporting criteria.

v. Review of updated investigators' brochures or package inserts.

vi. Review of protocol deviations.

vii. Complete translations of consent forms, diaries, and advertisements to appropriate languages as needed.

viii. Review of research for which a transfer of IRB oversight is requested. The review of each transferred study will be considered an initial review, with additional requirements as described in Section 3.E.iii.

ix. Continuing review of the Studies and Investigators.

2. RESPONSIBILITIES OF QUORUM

A. **Quorum's Primary Duty.** As set forth in 21 CFR § 56.102(g) and 45 § CFR §§ 46.102(g), 46.109 and 46.111, Quorum's primary duty is to protect the rights and welfare of "human subjects," a term defined by 21 CFR § 56.102(e) and 45 CFR § 46.102(f). Nothing in this agreement will be construed to limit Quorum's independence to take actions necessary to protect the rights and welfare of human subjects, or to alter Quorum's primary duty to human subjects.

B. **Compliance with Applicable Laws and Regulations.** Quorum shall perform the Services hereunder in compliance with applicable federal and state laws and regulations governing IRBs and research with human subjects, including the United States Food and Drug Administration ("FDA") Regulations 21 CFR Parts 50 and 56 and the United States Department of Health and Human Services ("DHHS") Regulations 45 CFR Part 46.

C. Notification Requirements. Quorum will promptly notify Institution of any (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with pertinent regulations or Board determinations, (iii) suspension or termination of Board's approval of the Study or (iv) other issues as requested by Institution.

3. RESPONSIBILITIES OF INSTITUTION

A. **General.** In keeping with the requirements of 21 CFR § 56.112 and 45 § CFR 46.112, Institution cannot approve a Study that has been disapproved by Quorum if Quorum is providing IRB Services to the Institution for that Study. Institution may, however, disapprove any Study approved by Quorum. Institution agrees to abide by requirements imposed by Quorum's IRB and shall use its best efforts to ensure that the Studies performed by Institution shall be conducted in accordance with such requirements.

B. **Investigators and Study Staff.** Institution shall ensure that the investigators and other staff at Institution who are conducting Studies under Quorum purview are appropriately qualified and meet Institution's standards for eligibility to conduct research. Institution shall ensure that investigators conducting research at Institution receive proper initial and continuing education related to human subject protection.

C. **Review of Clinical Trial Agreements.** Institution shall ensure that any Clinical Trial Agreement (CTA) and the approved consent form do not conflict regarding the plan for compensation for injury to subjects. Institution will inform Quorum of its procedures to resolve such conflicts. In the event of a conflict between the CTA and the consent form, the research will not commence until the conflict is resolved in a way acceptable to both Institution and Quorum.

D. **Notification Requirements.** Institution agrees to notify Quorum of all communications to and from the FDA, the Office for Human Research Protections (OHRP) and any other applicable federal and state regulatory agencies regarding the Studies under Quorum's oversight. Institution also agrees to notify Quorum of all research compliance/study-related issues concerning investigators who have submitted studies to Quorum for review. Additionally, Institution agrees to notify Quorum of all research compliance/study-related problems including any communications from research participants that are reported to Institution.

E. **Site Match Participation.** Quorum maintains a Site Directory service ("Site Directory"), which is used by sponsor and contract research organizations to select site locations for Studies. The Site Directory includes data Quorum collects during its experience working with a given site. Information included relates to turnaround times, enrollment, and responsiveness. In addition, the Site Directory identifies the therapeutic and disease state expertise at sites. Institution agrees to have its name included in the Site Directory.

F. **Research Submission Requirements**

i. Required Documents. Investigators affiliated with Institution must follow Quorum's standard submission requirements to initiate the Study review process. All required forms are available at http://www.quorumreview.com. Each Study shall be submitted to Quorum with an accompanying document indicating the existence of this agreement. Investigators may use the Institutional Jurisdiction Waiver Form (or equivalent form if Quorum forms are updated) or the parties may develop an Institution Cover Page to be submitted in lieu of the Institutional Jurisdiction Waiver Form.

ii. Consent Form Template. The parties may choose to develop specific language for portions of the informed consent ("Consent Form Template"). If a Consent Form Template is reviewed and agreed to by Quorum, Institution understands that the IRB has the ability to deviate from the template if it is determined to be necessary given the context of the study or other factors.

iii. Consent Form Revisions. The parties acknowledge that for multi-site Studies, Quorum approves the Consent Form(s) to be used by all sites ("Model Consent Form"). The approved Model Consent Form(s) is updated with site-specific information when a site is approved. Institution agrees to limit unique revisions to the approved Model Consent Form(s) for multi-site Studies to the following three sections: 1. Compensation for Injury; 2. Payment & Reimbursement; & HIPAA Authorization.

iv. Responses to Quorum. The Parties agree that timely responses to requests from Quorum staff will ensure reasonable timelines for IRB review of Studies. To that end, Institution commits to use its best efforts to respond within the timeline associated with each request from Quorum staff and the IRB.

v. Transfer of IRB Oversight.

a. Required Documents for Transfers of IRB Oversight. Quorum requires additional information for Studies submitted with a request to

transfer IRB oversight. The documents required will be based on Quorum's existing procedures at the time the transfer of IRB oversight occurs. Quorum may request additional documentation for transferred Study submissions, including: minutes of IRB meetings during which the Study was reviewed; reports of unanticipated problems involving risks to human subjects and others; reports of IRB-conducted audits, if any; and correspondence with the investigator, sponsor and/or Federal Agencies. If Institution is unable to produce documents requested by Quorum, a written explanation as to why the document cannot be produced should be provided.

b. Identification of Studies for Transfers of IRB Oversight. The parties will mutually agree on the Studies that will be transferred to Quorum for IRB oversight. If the parties determine it is necessary based on volume of Studies submitted as transfers, a schedule for review will be documented in writing.

c. Effective Date of Transfer. Unless otherwise agreed by the parties, the transfer of IRB oversight will be effective, on an individual Study basis, as of the date of review and approval of each Study by Quorum.

4. CONFIDENTIALITY

A. **Definition.** The term "Confidential Information" shall mean any information that the receiving party ("Recipient") receives from or on behalf of the disclosing party (for purposes of this section, the "Owner") or which the Recipient derives therefrom in connection with the performance of Services hereunder, including any information, data or reports the Recipient may generate and including, without limitation, proprietary products, protected health information of individuals, technology, literature, clinical or other research, regulatory data or plans, clinical data or plans, proposal plans, product plans, IRB and consultant rosters, standard operating procedures, training materials, product candidates, fee structures and customer and vendor data and relationships associated with the products and services of the Owner, whether disclosed in writing, orally, electronically, or by drawings. Further, any information learned through observation during visit(s) to the other party's facilities shall also be deemed Confidential Information subject to such obligations.

B. **Obligations.** Recipient agrees to maintain the confidentiality of such information and not to disclose it to any third party without prior authorization from Owner. Recipient shall exercise at least the same degree of care as it customarily takes to preserve and safeguard its own proprietary information, which in no event shall be less than a reasonable standard of care. Recipient has obtained or will obtain, prior to commencement of work hereunder, written agreements with its employees, contractors, IRB members, consultants, and agents to maintain the confidentiality of such Confidential Information as is exchanged herein. Each party shall promptly advise the other in writing if either learns of any unauthorized duplication, use or disclosure of Confidential Information.

C. **Survival of Obligations.** The obligations of Recipient with regard to Confidential Information shall continue for a period of ten (10) years, beyond the termination or expiration of this agreement.

D. **Exclusions.** These obligations of non-disclosure shall not apply to Confidential Information that:

i. Is already known to Recipient as shown by its prior written records;

ii. Is or becomes publicly available through no fault of Recipient;

iii. Is received from a third party which has the legal right to disclose it to Recipient; or

iv. Is required by law, court order, subpoena, government order or request to be disclosed, provided that Recipient shall, as promptly and reasonably possible and prior to any such disclosure, give written notice to Owner and shall cooperate with Owner if the Owner elects to contest and/or avoid such ordered disclosure. If Recipient is nonetheless legally compelled to disclose the Confidential Information, Recipient shall disclose only that portion of the Confidential Information which, in the opinion of its legal counsel, is legally required to be disclosed. Recipient will exercise reasonable efforts to ensure that any such information so disclosed will be accorded confidential treatment by the said court or tribunal.

E. **Ownership.** All Confidential Information shall remain the exclusive property of the Owner and shall be returned by the Recipient to the Owner promptly upon written request of the Owner, together with all copies thereof, except the Recipient may retain one (1) archival copy as required by law or its written procedures. Upon the request of the Owner, the Recipient shall destroy and certify to the Owner the destruction of any and all documents, papers, electronic or other media and materials and notes thereon, including copies, summaries or reproductions thereof, that contain Confidential Information of the Owner. The return and/or destruction of such Confidential Information shall not relieve the Recipient of its other obligations under this agreement.

F. **Use of Names and Other Information.** Notwithstanding the forgoing, Institution agrees that Quorum may include the Institution's name , logo, and other information about the Institution in Quorum's Site Directory, on Quorum's website an in Quorum's promotional materials. Additionally, nothing in this agreement shall be construed to restrict a party from disclosing that Quorum reviews Studies for the Institution.

5. **NOTICE**

All notices relating to the terms of this agreement shall be delivered personally, by facsimile, by e-mail, by registered or certified first class mail, or by overnight courier service to the contact addresses set forth below. Notice shall be effective upon receipt if personally delivered, delivered by e-mail or delivered by facsimile; upon the third business day following the date of mailing by registered or certified first class mail; or on the first business

day following the date of delivery to the overnight courier. A party may change its address listed below by written notice to the other party.

If to Institution: [Name
Address
Telephone
Email]

If to Quorum: Quorum Review, Inc.
Attention: Vice President of Regulatory and Legal Affairs
1501 Fourth Avenue, Suite 800, Seattle, WA 98101
Email: legal@quorumreview.com
Facsimile: (206) 448-4193

6. PAYMENT FOR SERVICES

A. **IRB Review Fees.** Quorum will charge for Services in accordance with its published fees in effect at the time that Services are rendered. The price list in effect at the time of initial review of a Study shall apply for the duration of the Study, regardless of subsequent changes to the applicable Quorum Price List unless specifically agreed otherwise in writing by both parties.

B. **Institution-Sponsor Contract.** Institution must maintain a contractual agreement with each sponsor and/or investigator in which the sponsor and/or investigator agrees to make payments as specified in this Section directly to Quorum for Services rendered.

C. **Billing.** Quorum shall bill sponsors, investigators, or their agents, for Services rendered as directed upon the applicable submission form(s). If Quorum does not receive payment within ninety (90) days of invoicing, Institution shall be responsible for payment of such Services regardless of the original billing contact instruction(s) noted in the submission form(s).

D. **Invoices.** If the Institution will be billed, as described in Section 6.C. above, invoices will be emailed in PDF format to the email address provided for the Institution contact. Each invoice will include an itemized list of the Services provided.

E. **Payment.** Payments shall be remitted to Quorum either by electronic fund transfer or by mail to the lockbox address on the invoice. The payment shall be made payable to Quorum Review, Inc., Tax I.D. No. 91-1528508 and reference Quorum's invoice number(s).

Wire payments to: Bank Name: US Bank
Routing Number: 125000105
Account Number: 153591346447
Beneficiary: Quorum Review, Inc.

Or, mail checks to: Quorum Review, Inc.
PO Box 84572
Seattle, WA 98124-5872

7. TERM AND TERMINATION

A. **Term.** The term of this agreement shall commence on the date of this agreement, and shall continue until such time as either party gives sixty (60) days written notice of termination. Notwithstanding the foregoing, in the event that either party is in default in the performance of any of its obligations under this agreement, and the default has not been remedied within thirty (30) days after the date of notice in writing of such default, the party not in default may terminate this agreement immediately by written notice.

B. **Termination.** Notwithstanding the immediately preceding paragraph, the parties specifically recognize that 21 CFR § 56.109(f) and 45 CFR § 46.109(e) require "an IRB [to] conduct continuing review of research . . .not less than once per year." Therefore, termination of this agreement shall not affect Quorum's obligation to conduct continuing review for studies approved hereunder. Upon termination, Quorum will continue its oversight of active studies until closure, unless otherwise mutually agreed to by the parties. If Institution requests that active studies be transferred to Institution or other IRB, an additional fee equal to Quorum's annual continuing review fee shall be charged to Institution for each active agreement transferred.

8. SECURE PORTAL

Quorum maintains a secure portal (the "Portal") accessible through the internet. Quorum receives submission documents and posts IRB correspondence and approval documents on the Portal. Institution acknowledges that when Quorum grants Portal access to Institution employees or agents, Institution and those individuals will be obligated to abide by the Terms of Use set forth at http://www.quorumreview.com, or any website owned by Quorum, including the terms relating to confidentiality, submission standards, limited license of use, warranties and disclaimers. To the extent the terms of this agreement conflict with the provisions of the Terms of Use, this agreement shall govern. Institution also acknowledges that it is Institution's obligation to notify Quorum when the access of an Institution employee or agent should be disabled for any reason.

9. REPRESENTATIONS AND WARRANTIES

A. Quorum represents and warrants that it shall utilize independent discretion and judgment in discharging its responsibilities and shall perform all Services in a professional and efficient manner and in material compliance with generally accepted industry standards and applicable federal, state, local, or provincial laws, rules and regulations, and Quorum's standard operating procedures.

B. Quorum represents and warrants that it has full accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

C. The parties hereby certify that neither they, nor any of their employees, agents or independent contractors have been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 335a(a) or (b). Quorum agrees to promptly disclose in writing to Institution if Quorum, or any employee, Board member,

consultant, or agent is debarred or if any action or investigation is pending or, to the best of Quorum's knowledge, threatened, relating to the debarment of Quorum or any person performing Services related to this agreement.

D. The parties hereby certify that they have not and will not knowingly use in any capacity the Services of any individual, corporation, partnership, or association which has been debarred under section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 335a(a) or (b).

E. The parties have the full power and authority to enter in to this agreement and to perform their obligations under this agreement.

10. INSURANCE

Each party will maintain, for the duration of this agreement, insurance in an amount reasonably adequate to cover its obligations hereunder, and upon request, each party will provide to the other party a certificate of insurance showing that such insurance is in place. The terms of this section and the obligation of the parties hereunder shall survive termination of this agreement and the completion of all obligations of Institution and Quorum under this agreement.

11. MISCELLANEOUS

A. **Entire Agreement; Amendments.** This agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and there are no agreements, relationships or undertakings with respect thereto or implied, other than as set forth herein. This agreement may be amended from time to time upon the mutual written agreement of the parties.

B. **Waiver of Breach.** Neither the failure nor any delay on the part of either party to exercise any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or privilege preclude any other or further exercise thereof, or the exercise of any other right, power or privilege. In the event a party should waive any breach of any provision of this agreement, it shall not be deemed or construed as a waiver of any other breach of the same or different provisions.

C. **Severability.** In the event that any court of competent jurisdiction shall hold any part, term, or provision of this agreement invalid or unenforceable, such holding shall not invalidate or render unenforceable any other provision hereof and the rights and obligations of the parties shall be construed and enforced as if this agreement did not contain the particular part, term or provision held to be invalid.

D. **Governing Law.** This agreement is governed by the laws of the State of Washington without regard to such state's conflict of laws principles. Venue for any lawsuit, claim, or other proceeding between the parties arising under this Agreement shall be exclusively in the state and federal courts in Seattle, King County, Washington.

E. **Assignment.** This agreement may not be assigned or transferred by either party without the prior written consent of the other party, which shall not be unreasonably withheld.

F. **Force Majeure.** No default, delay, or failure to perform on the part of either party shall be considered a default, delay, or failure to perform otherwise chargeable, hereunder, if such default, delay, or failure to perform is due to cause or causes beyond the reasonable control of such party, including, but not limited to, strike, lockouts, or inactions of governmental authorities; epidemics; war; embargoes; fire; earthquake; acts of God; or default of a common carrier. In the event of such default, delay, or failure to perform, any date or times by which either party is otherwise scheduled to perform shall be extended automatically for a period of time equal in duration to the time lost by reason of the excused default, delay, or failure to perform.

G. **Relationship of the Parties.** Each party's relationship with the other is and shall be that of an independent contractor, and no partnership, joint venture, co-venture, employer/employee, principal/agent, master/servant or other similar relationship is created, or intended to be created, hereby. Neither party is nor shall be the agent or employee of the other, and neither party has authority to act on behalf of the other in any matter except to the extent expressly agreed upon in writing.

H. **Headings.** The headings used in this agreement are inserted only for convenience, and shall not be construed in the interpretation of this agreement.

I. **Survival.** Sections 4, 6, and 8-11 shall survive expiration of termination of this agreement.

J. **Authority to Sign.** The persons who sign the Agreement on behalf of the Institution and Quorum are acting within the scope of their authority as agents.

K. **No Third Party Beneficiaries.** This agreement is not intended to and shall not confer upon any other person or business entity, other than the parties hereto, any rights or remedies with respect to the subject matter of this agreement.

Remainder of Page Intentionally Left Blank

IN WITNESS WHEREOF, the parties thereto have caused this Agreement to be duly executed by proper persons thereunto duly authorized.

[INSTITUTION NAME]	**QUORUM REVIEW, INC.**
_____	_____
(Authorized Signature)	(Authorized Signature)
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

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Quorum Review
Institution Cover Page

(Customized for each Institution with an MSA requiring handling outside of Quorum's standard operating procedures. All fields are optional and modifiable to fit the terms of the MSA)

Institution Logo Here

For prompt assessment and Board review, Institution site submissions are submitted with the Site Information Questionnaire (SIQ) and should contain general elements as noted in the Site Submission Checklist found on Quorum's website at www.quorumreview.com. Including the Institution Cover Page will ensure proper handling of your initial site submission.

NAME OF INSTITUTION	
PRINCIPAL INVESTIGATOR	
PROTOCOL NUMBER	
SPONSOR NAME	

Investigator Unique / Modified Consent Forms

If you are a site participating in a central study for which Quorum is the central IRB, the Study Manager, or sponsor for the above protocol, can provide you with the current approved copy of the model consent form for review. *Please indicate below how your consent form should be handled for the above study.*

☒ This Institution **HAS** client template consent language with Quorum. If this is a single-site or PI-generated study, you do not need to check any additional boxes below.

If you are a site in a central study for which Quorum Review is the central IRB, please check one of the boxes below.

For this study, my Institution requests to:

a. ☐ Use the model consent form only and do not include our institution's template consent language.

b. ☐ Use the model consent form incorporating our institution's template consent language (sponsor approval must be included).

c. ☐ Use the model consent form incorporating some our institution's template consent language for the sections listed here (sponsor approval must be included):

d. ☐ Use the model consent form including our institution's template consent language **and** additional unique changes not previously negotiated (tracked consent form is attached along with rationale and sponsor approval).

Acknowledgement by <<Institution Name>>

The Investigator(s) named at the beginning of this form are authorized to conduct the above referenced investigational research study in this institution under the jurisdiction of Quorum Review.

Signature of <<Institution Official Name>> or authorized Designee: _____ Date: _____

Please give portal account access to the following individual:

Name:

Email address:

THIS SECTION DESCRIBES CURRENT HANDLING REQUIREMENTS FOR THE INSTIUTION ABOVE AND IS FOR QUORUM USE ONLY

<<Insert instructions to staff here>>

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Quorum

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Suite 800
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Client Guide to Consent Form Evaluation

This guide details the process used by Quorum Review to evaluate consent forms submitted by clients for Board review. If you have any questions about this process, please feel free to contact Quorum Review.

Regulations, Laws and Guidance

Quorum evaluates submitted consent forms to confirm that the language is in compliance with applicable regulations, laws, and guidelines in the United States and/or Canada. In doing so, we utilize federal and state regulations, FDA and OHRP guidance, ICH guidelines, and other sources. A list of our most commonly used references is provided below.

Regulations and Guidance

FDA (U.S.)
FDA 21 CFR 50.20
FDA 21 CFR 50.25
FDA 21 CFR 50.27
A Guide to Informed Consent – Information Sheet

HHS (U.S.)
HHS 45 CFR 46.116
HHS 45 CFR 164.508
HHS 45 CFR 46, Subpart D

OHRP (U.S)
Office for Human Research Protections (OHRP), Secretary's Advisory Committee on Human Research Protections (SACHRP), Appendix D

TCPS 2 (Canada)
TCPS 2, Article 3
TCPS 2, Article 5
TCPS 2, Article 12

Personal Information Protection and Electronic Documents Act (PIPEDA) (Canada)
S.C. 2000, c. 5

AHRPP
AHRPP E.I.6.B.

U.S. State Laws

California
California Civil Code Section 56.11
California Health and Safety Code Section 24173

Indiana
Indiana Code 16-39-1-4

New York
New York Civil Rights Law Section 79-I

ICH Guidelines

ICH 4.8.4
ICH 4.8.7
ICH 4.8.8
ICH 4.8.9
ICH 4.8.10
ICH 4.8.11
ICH 4.8.12

In addition to evaluating the template language for compliance with applicable regulations, laws, and guidelines, Quorum also reviews client template language to address Quorum Review's guidelines for participant protection and formatting/administrative needs. For example, consent form may be revised to allow for site-specific modifications to the consent form.

Quorum

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Quorum's Editing Processes

1. Quorum Review applies any required edits to the consent form(s) provided by clients using the "Track Changes" feature in Microsoft Word. To simplify review, any minor changes to formatting that do not impact content or meaning are not tracked or documented.
2. After the Board has reviewed and approved the consent form(s), Quorum sends tracked and clean versions of each edited consent form to the client for review. (The tracked version shows Quorum's suggested changes, tracked in with Word's Track Changes feature. The clean version also includes those proposed changes, but the changes are not "tracked in" the document—the changes are included without any tracking.)
3. After review, if the client has any additional changes to request to the consent form(s), they should provide those changes as tracked-in revisions to the **clean** Word document provided and should include written rationale for each of the requested changes. The rationale may be provided in a document separate from the revised consent form, or it may be provided in comments inserted into the revised consent form. Quorum may request clarification if the client does not provide rationale.
4. Quorum Review evaluates the client-proposed changes and accompanying rationale. If the changes meet Quorum's requirements, they will be incorporated as appropriate. Changes to the consent form will be sent through expedited review for approval. This process may be repeated until the consent form language is accepted.

Superscripts

To assist with communication, edits to consent form language are followed by a superscript number representing the rationale for the specific change. Please see below for the list of superscripts and their rationales.

Rationale for Change	
#1	To reflect regulations, laws, ICH guidelines, or standard research-related guidance (such as FDA Information Sheets)
#2	To reflect protocol specifications
#3	To reflect Board preferences regarding language that may be seen as coercive or overly reassuring (e.g., the Board may prefer the use of "study drug" instead of "study medication")
#4	To reflect words, phrases, paragraphs, or changes specifically requested by the client
#5	To remove duplication of information
#6	To improve participant protection and/or safety
#7	To move information from another area of consent form
#8	To change point-of-view
#9	To simplify language for readability, clarification, or consistency

Umbrella Institutional Authorization Agreement

Organization Providing IRB Review: Quorum Review, Inc. (d/b/a Quorum Review IRB, "Quorum")
Quorum's IRB Registration #: IRB00003226
OHRP Federalwide Assurance ("FWA") #, if any: N/A

Name of Institution Relying on the Designated IRB ("Institution"):
Institution's FWA #:

This Agreement is effective as of the last date of signature below. The Officials signing below agree that Institution shall rely on Quorum for review and continuing oversight of all of the human subjects research ("Research") submitted by the Institution. The review performed by Quorum will meet the human subject protection requirements under applicable Regulations and the terms of the Institution's OHRP-approved FWA. Institution remains responsible for ensuring compliance with Quorum's determinations and with the terms of its FWA. Each Research submission made to Quorum under this agreement shall be accompanied by an Institutional Jurisdictional Waiver ("IJW") Form noting the existence of this agreement. Alternatively, the Institutional and Quorum may develop an Institutional Cover Page ("Cover Page") to be used in lieu of an IJW.

Quorum will follow written procedures for reporting its findings and actions to the PI, Sponsor, and appropriate officials at the Institution. Institutional Officials will be noted on the IJW or Cover Page. Institution agrees to notify Quorum of all communications to and from the FDA, the OHRP and any other applicable federal and state regulatory agencies regarding the Research under Quorum's oversight. Institution also agrees to notify Quorum of any research compliance/study-related issues concerning investigators who have submitted studies to Quorum for review. Additionally, Institution agrees to notify Quorum of any research compliance/study-related problems including any communications from research participants that are reported to Institution.

Each organization listed below ("Party") is authorized to exchange information pursuant to this Agreement and agrees to treat such information as confidential (Confidential Information). No Party shall disclose Confidential Information received pursuant to this Agreement to any individual or entity other than another Party without prior written approval of all Parties. Notwithstanding the foregoing, nothing in this Agreement shall be construed to restrict a Party from disclosing Confidential Information as required by law, subpoena, court order, or other governmental order or request, provided that the party facing such order or request notifies the Disclosing Party and assists in obtaining a protective order, if necessary. Additionally, Institution agrees that Quorum may include the Institution's name and other information about the Institution in Quorum's Site Directory. The information included in the Site Directory will be related to Quorum's experience working with the Institution. Nothing in this agreement shall be construed to restrict a party from disclosing that Quorum reviews Studies for the Institution.

Quorum or its authorized representatives shall be permitted to:

1. Examine and inspect Institution's facilities used for the performance of its research, including storage and use of any investigational products;
2. Observe the conduct of the research performed at the Institution;
3. Inspect and copy all documents relating to its studies, including study records and informed consent documents, investigational product logs, required licenses, certificates and accreditations; and,
4. Interview all necessary personnel involved in the research conduct of its studies.

This document must be kept on file by all parties and provided to FDA, OHRP, and/or other applicable regulatory agencies upon request. This Agreement may be executed in any number of counterparts, either in original or faxed form.

Signature page follows.

Umbrella Institutional Authorization Agreement

[INSTITUTION]	QUORUM REVIEW, INC.
_____	_____
(Authorized Signature)	(Authorized Signature)
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

Institutional Authorization Agreement

Organization Providing IRB Review: Quorum Review, Inc. (d/b/a Quorum Review IRB, "Quorum")
Quorum's IRB Registration #: IRB00003226
OHRP Federalwide Assurance ("FWA") #, if any: N/A

Name of Institution Relying on the Designated IRB ("Institution"):
Institution's FWA #:

This Agreement is effective as of the last date of signature below. The Officials signing below agree that Institution shall rely on Quorum for review and continuing oversight of the following human subjects research study:

Name of Research Study ("Study"):
Name of Principal Investigator ("PI"):
Name of Sponsor:
Name of Funding Agency: Award Number, if any:

The review performed by Quorum will meet the human subject protection requirements of the Institution's OHRP-approved FWA. PI is responsible for ensuring compliance with Quorum's determinations. Institution remains responsible for ensuring compliance with Quorum's determinations and with the terms of its OHRP-approved FWA. Each Research submission made to Quorum under this agreement shall be accompanied by an Institutional Jurisdictional Waiver ("IJW") Form noting the existence of this agreement.

Quorum will follow written procedures for reporting its findings and actions to the PI, Sponsor, and appropriate officials at the Institution. Institutional Officials will be noted on the IJW. Institution agrees to notify Quorum of all communications to and from the FDA, the OHRP and any other applicable federal and state regulatory agencies regarding the Study. Institution also agrees to notify Quorum of any research compliance/study-related issues concerning the PI. Additionally, Institution agrees to notify Quorum of any research compliance/study-related problems, including any communications from research participants that are reported to Institution.

Each organization listed below ("Party") is authorized to exchange information pursuant to this Agreement and agrees to treat such information as confidential (Confidential Information). No Party shall disclose Confidential Information received pursuant to this Agreement to any individual or entity other than another Party without prior written approval of all Parties. Notwithstanding the foregoing, nothing in this Agreement shall be construed to restrict a Party from disclosing Confidential Information as required by law, subpoena, court order, or other governmental order or request, provided that the party facing such order or request notifies the Disclosing Party and assists the Disclosing Party in seeking a protective order, if necessary. Additionally, Institution agrees that Quorum may include the Institution's name and other information about the Institution in Quorum's Site Directory. The information included in the Site Directory will be related to Quorum's experience working with the Institution. Nothing in this agreement shall be construed to restrict a party from disclosing that Quorum reviews Studies for the Institution.

Quorum or its authorized representatives shall be permitted to:

1. Examine and inspect Institution's facilities used for the performance of this research, including storage and use of any investigational products;
2. Observe the conduct of the research performed at the Institution;
3. Inspect and copy all documents relating to the Study, including study records and informed consent document(s), investigational product logs, required licenses, certificates and accreditations; and,
4. Interview all necessary personnel involved in the research conduct of the Study.

Institutional Authorization Agreement

This document must be kept on file by all parties and provided to FDA, OHRP, and/or other applicable regulatory agencies upon request. This Agreement may be executed in any number of counterparts, either in original or faxed form.

[INSTITUTION]

(Authorized Signature)

Name: _____

Title: _____

Date: _____

QUORUM REVIEW, INC.

(Authorized Signature)

Name: _____

Title: _____

Date: _____

PRINCIPAL INVESTIGATOR

(Authorized Signature)

Name: _____

Title: _____

Date: _____