Quorum

Institutional Start-Up Package

Your First Step to Working with Quorum Review IRB

May 2017

Institutional Start-Up Package
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Dear Colleague:

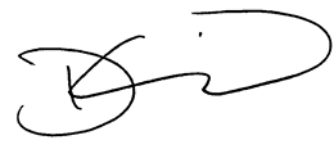
Thank you for your interest in partnering with Quorum. Quorum is a leader in providing ethical review with more than 25 years of experience in human research protections and is committed to working with your Institution to facilitate human subject research. Quorum understands there are specific processes unique for every institution, which is why our dedicated Institutions Support Team is available to guide you through our process and answer any questions you have about IRB review at Quorum.

Enclosed is a step by step process for working with Quorum and our Institution IRB Reliance Agreement. This agreement outlines the responsibilities of Quorum and your Institution consistent with the Association for the Accreditation of Human Research Protection Programs (AAHRP) standards. It also serves as the required agreement if you are a Federal Wide Assurance (FWA) holding Institution conducting federally funded research.

The signed agreement can be emailed to institutions@quorumreview.com and Quorum will contact you shortly thereafter. If you have questions at any time please call me at 206-436-3297. I will partner closely with you and your team as we work through the process of establishing our relationship.

Thank you again for your interest in Quorum Review. We look forward to working with you and helping to bring your expertise to our process.

Warm Regards,



David H. Kim
Institutional Account Executive
Institutions@quorumreview.com
206-436-3297

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SETTING UP A RELATIONSHIP WITH QUORUM REVIEW IRB

Below outlines the steps in setting up a partnership with Quorum. Any questions along the way? Contact Quorum's Institutional Account Executive at 206-436-3297 or Institutions@quorumreview.com.

Getting started with Quorum:

Step 1: Execute an Institution IRB Reliance Agreement

Purpose: An Institution IRB Reliance Agreement (IIRA) spells out the terms of the working relationship with Quorum Review IRB. As an AAHRPP accredited IRB, we follow all the AAHRPP standards.

Tools provided: Quorum has provided in this package a template IIRA. Please feel free to propose any revisions to meet the needs of your institution.

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

Step 2: Meet your Institutional Account Manager

Purpose: Assigning a single point of contact to your institution provides consistency in the management of your account and ensures seamless execution of established special handling requirements.

Step 3: Draft a Cover Page with Quorum

Purpose: Designing a custom cover page for your institution will ensure the proper handling of your initial site or study submission, such as holding your submission or approval documents until Quorum receives approval from your institution to proceed. Quorum will work with you to identify special handling requirements necessary to respect your institution's processes.

Step 4: Pre-Approved Consent Form Template Language

Purpose: Establishing the consent form during study start-up can be complicated. In order to streamline this process, Quorum can review and pre-approve template consent language that your institution prefers. This is especially helpful for language that is often institution-specific, such as privacy language, injury compensation language, and emergency contacts.

Tools provided: If you would like to arrange for pre-approved template language, when you submit to Quorum Review please also 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 consent form development guidance. Please contact Quorum's Institutional Account Executive at 206-436-3297 or Institutions@quorumreview.com.

Where to send the completed information: Once your template consent form is complete please submit to Quorum's Institutional Account Executive at Institutions@quorumreview.com.

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F/ 206 448 4193

Benefits of establishing a working relationship with Quorum:

1. **Single point of contact**
   Quorum will assign your institution a dedicated Institutional Account Manager as the single point of contact for your study staff.

2. **Ease of submissions**
   The cover page will simplify the submission process for your investigator and identify the specific processing requirements established for your institution.

3. **Opportunity to participate in current or future studies under Quorum's purview**
   Being a member of Quorum's Platinum program will allow your institution greater access to participate in industry sponsored studies under Quorum's purview. For more information about the Platinum Program, please contact Quorum's Institutional Account Executive at Institutions@quorumreview.com.

4. **Respect for your processes**
   Your researchers can submit studies on your institution's submission forms, and Quorum's staff will elicit any additional information needed. After the study has started, your institution will receive notice of significant adverse events and, in the event an incident has to be reported to federal agencies, you will have the opportunity to review the draft letter and provide feedback prior to Quorum sending the letter to the appropriate agency.

5. **Customized and tailored handling of your consent forms**
   Quorum will insert identified Institution and Board approved template language in all consent forms from your Institution. Quorum will also meet all necessary local requirements for your institution.

6. **Established relationship with all the major pharmaceutical companies**
   Quorum has an extensive list of pharmaceutical clients that are satisfied with the custom services we are able to provide, that can be an ideal fit for any client.

7. **Training provided for your staff**
   Quorum understands that there is a learning curve with utilizing a new service. To that end, we are willing to provide customized training or webinars at your convenience—or we could arrange a visit to your institution. If interested, please send an email to your Institutional Account Manager or Quorum's Institutional Account Executive at Institutions@quorumreview.com.

8. **Our doors are always open**
   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. As back-up for your single point of contact, our call center is available from 5:00 AM to 5:00 PM PT, with an answering service available all night.

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Institution IRB Reliance 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"**), and [**Institution Name**] a [State] [corporation/limited liability company/non-profit].

Name of Organization Providing IRB Review: Quorum Review, Inc.

- **IRB Registration #:** IRB00003226
- **Federalwide Assurance (FWA) #:** N/A
- **Address:** 1501 4th Ave., Seattle, WA 98101

Name of Institution Relying on the Designated IRB ("Institution"):

- **Federalwide Assurance (FWA)# or N/A:** [FWA# or N/A]
- **Instituion Contact:** [Contact name, phone number, and email address]
- **Contact Address:** [Address of principal place of business]
- **Responsible Official:** [Responsible Official name]
- **Please identify all Member Institutions, Affiliates, and/or Components encompassed in this agreement:**
    1. [List all Affiliates and/or components covered under this agreement or indicate N/A]

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

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

1. **Description of Services**

A. **Services.** Quorum will provide IRB review and 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 will 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 and other materials that require review by Quorum, including amended consent forms or other changes.

iv. Review potential unanticipated problems involving risk to participants or others, including serious and unexpected adverse events, reports of serious or continuing noncompliance, review of Investigational New Drug (IND) safety

reports and other events that qualify for reporting to the IRB under Quorum's reporting criteria. Quorum may suspend or terminate IRB approval incompliance with applicable laws, regulations, and guidelines and Quorum's procedures and policies.

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.F.vi.

ix. Continuing review of the Studies and Investigators.

x. Review, as requested, waivers for the requirement to obtain HIPAA authorization for the use and disclosure of Protected Health Information ("PHI").

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 and the Health Insurance Portability and Accountability Act of 1996 Regulations 45 CFR 164 Subpart E as applicable.

C. **Notification Requirements.**

i. Quorum shall promptly notify the currently-approved Principal Investigator (PI) of the study under review of all IRB decisions and shall make available to the PI all decision letters, approved consent forms, and other similar participant materials. Upon request, Quorum will provide applicable IRB meeting minutes pertaining to research study materials reviewed by Quorum for the Institution.

ii. Quorum will promptly notify the Principal Investigator and Institution's Responsible Official (i) if there is ever a suspension or restriction of the IRB's authorization to review studies; (ii) of changes in Quorum's operating procedures that might affect the Institution's reliance on Quorum; or (iii) of

changes in Quorum's Human Research Protection Program accreditation status.

iii. The parties acknowledge and agree that any reporting to regulatory agencies, including FDA and Office for Human Research Protections (OHRP), or oversight authorities in connection with any Study shall be the sole responsibility of Quorum, as the IRB of record; provided, however, Quorum shall (i) promptly notify Institution of its intent to submit any such report, (ii) provide a draft of its proposed report to the Institution for review at least seventy-two (72) hours prior to submission, and (iii) consider incorporating Institution's comments in its report if provided prior to submission, as Quorum deems appropriate.

D. **SiteMatch Participation.** SiteMatchis a service provided by Quorum intended to connect Sponsors and contract research organizations with sites participating in clinical trials. As part of SiteMatch, Quorum will provide to Sponsors the site's therapeutic and disease state expertise as well as efficiency metrics.

3. **Responsibilities of Institution**

A. **General Responsibilities.**

i. Compliance. The Institution is generally responsible for ensuring investigator compliance with the protocol, IRB determinations, applicable federal and state regulations, and sponsor requirements. The Institution agrees to provide all information required by Quorum in order to conduct its reviews, including local context issues relevant to the research protocol. The 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 and shall use its best efforts to ensure that the Studies performed by Institution are conducted in accordance with such requirements.

ii. Enrollment. Researchers at the Institution will not enroll individuals in research prior to review and approval by Quorum. When responsible for enrolling participants, the researchers will obtain, document, and maintain records of consent for each participant or each participant's legally authorized representative as stipulated by Quorum.

iii. Reporting. Researchers will report to Quorum any unanticipated problems involving risks to participants or others as well as instances of noncompliance and protocol deviations according to Quorum's reporting policy, and continue to provide Quorum data safety monitoring reports according to Quorum policy.

iv. Emergency Care. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal and state law. Institution is primarily responsible for safeguarding the rights and welfare of research participants, and participant's rights and welfare takes precedence over the goals and requirements of the research.

B. **FWA.** The Institution is responsible for obtaining an FWA if applicable to the research being conducted at the institution. The Institution is responsible to comply with the terms of its FWA as applicable. The Institution will notify Quorum promptly in writing if the status of the FWA is no longer in good standing with OHRP.

C. **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, and have appropriate resources to conduct the research. Institution shall ensure that investigators conducting research at Institution receive proper initial and continuing education related to human subject protection.

D. **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.

E. **Notification Requirements.** Institution agrees to notify Quorum of all communications to and from the FDA, 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.

F. **Research Submission Requirements**

i. Required Documents. Investigators affiliated with Institution will 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 ' Institutional Cover Page' indicating the existence of this agreement, and which identifies site specific requirements.

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. Proposed Changes. The Institution will report promptly to Quorum any proposed changes in the research. The Investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to study participants.

v. 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.

vi. 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 required documents are based on Quorum's existing procedures at the time the transfer occurs. The additional documents may include: 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, Institution will provide a written explanation as to why the documents cannot be produced.

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. **Joint Responsibilities**

A. **Confidentiality and Privacy**

i. Definition. Each party is authorized to exchange information consistent with this Agreement, and agrees to treat such information as confidential (Confidential Information). 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 performed under this agreement. Each party shall be authorized to provide confidential information created or provided for this Study to the Study sponsor or its representatives.

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.

ii. 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. Each party shall promptly advise the other in writing if either learns of any unauthorized duplication, use or disclosure of Confidential Information.

iii. Survival of Obligations. The obligations of Recipient with regard to Confidential Information shall continue for a period of five (5) years, beyond the termination or expiration of this agreement.

iv. 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;

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

d. 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.

v. 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.

vi. Use of Names and Other Information. Notwithstanding the forgoing,

Institution agrees that Quorum may include Institution's name in Quorum's directory of institutions in which Quorum provides IRB Services.

B. **Conflict of Interest Management.**

i. Institution may perform its own investigator conflict of interest analysis under its relevant procedures. Quorum will review provided institutional conflict of interest management plans, to the extent that they involve human subject protection considerations, such as conflict of interest disclosure language in the consent form. Quorum may request additional information regarding submitted conflict of interest information, or require additional action if Quorum deems necessary to protect human subjects. Quorum will promptly inform the Principal Investigator if Quorum determines additional requirements are necessary that extend beyond the institutional conflict management plan.

ii. Quorum will review all study-specific investigator conflicts of interest according to Quorum Standard Operating Procedures if Institution does not perform its own investigator conflict of interest analysis.

iii. Institution shall ensure implementation of the conflict of interest management plan and report noncompliance with the same.

C. **Record Keeping.** Quorum and Institution agree to maintain records in compliance with all applicable federal, state, and local regulations regarding record retention and agree to make records available as required by law.

D. **Inspection**

i. Quorum or its authorized representatives shall be permitted upon request to: (1) examine and inspect the 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 document, investigational product logs, required licenses, certificates and accreditations; (4) interview all necessary personnel involved in the research conduct of its studies and (5) audit or witness the process of informed consent occurring at the Institution in connection with a study to be reviewed under this agreement.

ii. Institution shall be permitted upon request to (1) obtain copies of all applicable IRB correspondence pertaining to activities hereunder, all Institution provided correspondence and documents relating to its studies reviewed by Quorum, Quorum's IRB roster, and any required certificates and accreditations, and (2) inspect Quorum's policies, procedures, and other information pertinent to board functions.

5. **General Terms and Conditions**

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 or until such studies are transferred and re-reviewed by the responsible IRB, 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.

C. **Payment for Services**

i. 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.

ii. Institution-Sponsor Contract. Institution will use its best effort to 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.

iii. Billing. Quorum shall bill the applicable party whether the sponsor, investigator, institution, or their agents, for Services rendered as directed upon the applicable submission form(s).

iv. 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.

v. 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

D. **Notices.** 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 Institution Contact address. 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 by written notice to the other party.

If to Quorum:	Quorum Review, Inc. Attention: President and COO 1501 Fourth Avenue, Suite 800, Seattle, WA 98101 Email: legal@quorumreview.com
If to Institution:	[Institution] Attention:[Title] [Address] Email:[Email Address]

E. **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.

F. **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.

6. **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.

7. **Miscellaneous**

A. **Entire Agreement and 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 4A, 5C, 5I-J, 6, and 7 shall survive expiration of termination of this agreement.

J. **Authority to Sign.** The persons who sign the Agreement on behalf of the Institution, as well listed affiliates or components, 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:

Institution IRB Reliance Agreement (IIRA)
Frequently Asked Questions

1. Is Quorum able to provide our Institution with guidance and IRB review services that address the new NIH policy on use of a single IRB (sIRB) for multi-site research?

Yes. Quorum has over 25 years of experience conducting multi-site research under the model outlined in the NIH mandate. Quorum has all the necessary processes in place and expertise to assist you in addressing the NIH sIRB mandate as well as facilitate overall research at your Institution. Our consulting division, Kinetiq, can provide customized assistance in developing policies and procedures for your institution.

2. Can Quorum assist our investigators in preparing grant applications that request NIH funding to cover the costs of outsourcing sIRB obligations to a commercial IRB?

Yes. The Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research requires grant applications include a detailed plan for utilizing a sIRB. This includes information, for example, regarding costs, fee structures, procedures for compliance, and communication plans. Quorum is ready to assist investigators in providing a detailed plan that justifies and accounts for the selection of Quorum as the sIRB.

3. The reliance agreement asks us to identify the Institution's "Responsible Official." Who is the "Responsible Official" at my Institution?

The Responsible Official is the individual who is legally authorized to act for your Institution, and on behalf of your Institution. If you are an FWA holding institution conducting research with federal funds, the Responsible Official is your Institutional Official who obligates the Institution to the terms of your FWA.

4. The reliance agreement asks us to identify all "components." What are components?

Components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the same legal entity or institution. The term *component* is specific to FWA holding Institutions, and components are listed on the applicable FWA, which can be accessed and identified in the HHS FWA Database.

5. How does the informed consent process work and will our institution be able to retain institution-specific language in the form?

Quorum understands institutions have their own specific consent language, such as language for reimbursement, costs, and HIPAA. Our study services team will work with you to identify and document necessary institution-specific language requirements on your *Institutional Cover Page*. We will subsequently use this document to ensure submissions made to Quorum under your Institution's IRB Reliance Agreement include the required Institution-specific language prior to approval.

6. Our IRB office coordinates the reviews of many other committees in our institution (conflict of interest, pharmacy, etc.); how will we coordinate these activities with your review?

Quorum utilizes the 'Institution Cover Page' to account for all ancillary reviews and institution specific permissions that are required prior to enrolling the first participant. This may include, for example, reviews by the investigational drug service, the radiation safety committee, or a billing officer. Each submission will indicate whether any ancillary review is required and whether it has been completed by the time of submission. If a review is required and has not been completed, Quorum will work with the Institution's authorized designee(s) to ensure the study team is not provided study documents until all requirements have been met.

7. At our institution, we maintain our own Conflict of Interest Committee. How will their reviews and findings affect Quorum's review?

Findings and management plans made by your Institution's Conflict of Interest Committee may be submitted and incorporated into Quorum's review to the extent they involve human subject protection considerations, such as disclosure language in the informed consent. Quorum may request additional information regarding submitted investigator conflict of interest information, or require additional action if Quorum deems necessary to protect human subjects. If the Institution does not perform and provide its own investigator conflict of interest analysis, Quorum will independently review all study-specific investigator conflicts of interest.

8. Who in our institution can receive notification of adverse events at our research site?

Anyone listed as an Institution Contact can be designated to receive notification of any study related submissions to Quorum, which would include reported adverse events or other safety information. With this notification, the Institution Contact can utilize Quorum's OnQ Portal to view the original source document as well as to track and view any resulting Board action.

9. Will Quorum notify our Institution of events reportable to federal agencies prior to sending?

Yes. Quorum provides your institution with a draft of the report that it intends to provide the applicable agency. Your institution will have a 72 hour review period prior to Quorum submitting the report. Quorum will consider incorporating your institution's comments in its report if provided prior to submission.

10. How do IRB review fees work, and what is the fee schedule for IRB review?

There is a fixed fee amount for each type of submission made to Quorum for a particular study, depending on the type of submission. For example, there is a separate price for IRB review of a new study versus the continuing review of a study. All fees for a particular study are fixed for the lifetime of the study when the study is initially submitted for review. This means the fees for a particular study will not increase during the life of the study, even if Quorum's pricing changes.

To get the most up to date price list, send an email to institutions@quorumreview.com.

11. Where do I get more information specific to how Quorum works with Institutions?

Please feel free to contact David Kim, Quorum's dedicated Institutional Account Executive, at 206-436-3297. Additionally, you can email institutions@quorumreview.com. We are happy to discuss other topic areas particularly relevant to institutions, such as the conflicts of interest review process, review of member/affiliate institutions, and Quorum's integration with your institutional processes.

You can find more information about Quorum's commitment to working with Institutions, and the processes undertaken to facilitate IRB review for Institutions, on our Institutions Website.

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

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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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

AAHRPP
AAHRPP
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.

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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