Institutional Site Start-Up Information

Welcome to Sterling IRB! We look forward to working with your institution. Sterling IRB is registered with the Department of Health and Human Services (DHHS) as IRB00001790 and complies with all federal regulations pertaining to the protection of human research participants. Sterling IRB is also a participating member of SMART IRB. As an Independent Review Board, Sterling IRB is able to serve as the IRB of record for institutions such as medical centers, academic institutions, and community hospitals if one of the following conditions is met:

1. There is no local IRB with jurisdiction.
2. The local IRB has jurisdiction but defers it to Sterling IRB in writing.

Sterling IRB is here to help make ceding review as easy as possible! Below is some helpful information to assist your institution in working with Sterling IRB. If you have additional questions, please email us at institutions@sterlingirb.com about your institution's specific needs.

➢ New Site Submission

The Submission Application for the Investigator/Site needs to be completed to initiate the review process for a new Principal Investigator/Site joining a study currently under Sterling IRB review or to change the Principal Investigator on a study currently under Sterling IRB review.

The following items should be submitted with the Submission Application for the Investigator/Site (*Note: The submission application will prompt you for these items*):

- CV for the Principal Investigator (signed, dated and current within two years)
- DEA Registration (if the study involves controlled substances)
- Supplemental Site Form (if the PI will conduct research at more than one location)
- Site Specific consent form(s) if the site will make changes (*other than the PI name, site information, and compensation information)* ***Please see* "Site Specific Informed Consent Language" *for consent submission guidelines***.
- IRB Jurisdiction Form
- IRB Authorization Agreement (if applicable)

Getting Started: In SilverLink, navigate to the PI/Site's study-site page for the study you would like to join. Under the **Actions** column on the left side of the screen, select "Start xForm" and select the Submission Application for the Investigator/site.

Please be sure to click "submit" on the final page of the form. You will receive a confirmation email regarding your submission. If you do not receive a confirmation email, please contact Sterling IRB.

You can access SilverLink from Sterling IRB's website, www.sterlingirb.com or directly at: www.sterlingirb.my.irbmanager.com.

➢ IRB Reliance Options

1. IRB Authorization Agreement (IAA)

The IAA establishes the relationship between Sterling IRB and the institution on a study-by-study basis.

Getting Started: The IRB Authorization Agreement (APP114), attached, has been partially completed with Sterling IRB's required information. Alternatively, you may provide your institution's form for Sterling IRB to complete.

How to Submit: The IRB Authorization Agreement should be submitted with the Submission Application for the Investigator/Site in SilverLink. The form may also be submitted to Site Start-Up via email to institutions@sterlingirb.com.

2. Master Service Agreement (MSA)

A Master Service Agreement (MSA) is a contract for doing business. It establishes the guidelines for a working relationship with Sterling IRB in more detail than an IRB Authorization Agreement and can apply to all studies submitted to Sterling IRB. The following items can be addressed within the MSA:

- Consent form language requirements
- Institution submission requirements
- Reporting or other unique requirements

Getting Started: The Master Service Agreement template, attached, may be revised as needed. You may alternatively provide your organization's template for review.

How to Submit: Please submit the completed MSA template to Site Start-Up by email at institutions@sterlingirb.com.

3. IRB Jurisdiction Form

This form is required to let Sterling IRB know how your local IRB will be ceding review to Sterling IRB including if your site/institution is a member of SMART IRB and has agreed to cede IRB review to Sterling IRB via the SMART IRB Master Common Reciprocal IRB Authorization Agreement.

Getting Started: The IRB Jurisdiction Form may be completed via the Submission Application for the Investigator/Site in Silverlink. The attached copy of the IRB Jurisdiction Form (APP210) can alternatively be completed prior to submitting the site to Sterling.

How to Submit: Forms completed through SilverLink are automatically routed to Site Start-Up. The form may also be submitted to Site Start-Up via email to institutions@sterlingirb.com.

➢ Site Specific Informed Consent Language

An institution participating in a study under Sterling IRB's review can request to add language or make changes to the informed consent as required by their site/institution.

Getting Started: A template of the Sterling IRB approved ICF(s) for the protocol can be found in the Study Attachments section of Silverlink. You may also request the template ICF(s) via email to institutions@sterlingirb.com. Using the Sterling IRB approved template(s) ensures you are using the most recent, IRB- and sponsor-approved language. Tracking your changes on the IRB-approved template(s) can significantly reduce the processing time for your submission.

- Your institution may choose one of the following options to proceed:

    1. Use the Sterling IRB approved ICF template with no changes.
    2. Use the Sterling IRB approved ICF template with provided tracked changes of your site's/institution's requested language. Site/Institution and sponsor approval will be required.
    3. Use the Sterling IRB approved ICF and incorporate your site's/institution's template language per the MSA agreement on file. (Site/Institution and Sponsor approval will be required).

**If additional language is required that is NOT provided in the MSA, please provide the ICF template with that language tracked in addition to the MSA approved language.*

4. Provide your site's/institution's approved ICF for the study in which Sterling IRB's consent requirements will be incorporated by our consent editor. (This option incurs a per-hour charge. Sterling IRB, Sponsor and site/institution approval are required).

How to Submit: Upload the site/institution specific consent form(s) to your submission application in SilverLink.

➢ Reporting and other Special Requests

If your institution has special requirements and reporting needs, we are happy to accommodate these requests.

Getting Started: Tell us about your institution's special requirements or reporting needs by sending an email to institutions@sterlingirb.com.

➢ Training of Institution Staff

SilverLink is Sterling IRB's secure, web-based portal. Users can submit materials for Sterling IRB review via dynamic smart forms and retrieve documents from Sterling IRB. We are happy to set up a training with your staff on how to use SilverLink.

Getting Started: To request a staff training please contact support@sterlingirb.com.

Sterling IRB is pleased to offer Collaborative Institutional Training Initiative (CITI) educational resources to participating investigators and their staff.

Getting Started: For additional information on this program, please contact us at citiadmin@sterlingirb.com.

Institutional Review Board (IRB) Authorization Agreement

Name of Organization Providing IRB Review: Sterling Institutional Review Board ("Sterling IRB")

IRB Registration #	IRB00001790
Federalwide Assurance (FWA) #	N/A
Address	6300 Powers Ferry Rd., Suite 600-351, Atlanta, GA 30339

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

Federalwide Assurance (FWA) #	
Address	
Name of Institutional Official:	

Name of Institution Contact (Individual Responsible for Administration of this IAA)	
Contact's Email Address	
Contact's Phone Number	

The Officials signing below agree that Institution shall rely on Sterling IRB for review and continuing oversight of the following human subjects research:

Name of Research Project:
Name of Principal Investigator:
Name of Sponsor:
Name of Funding Agency:
Award Number, if any:

The review performed by Sterling IRB will meet the human subject protection requirements of 45 CFR 46 and 21 CFR 50 and 56, as applicable. Sterling IRB will follow written procedures for reporting its findings and actions to the PI, Sponsor, and appropriate officials at the Institution. Relevant minutes of IRB meetings will be made available to the Institution upon request.

Institution remains responsible for ensuring compliance with Sterling IRB's determinations and with the terms of its OHRP-approved FWA. The Institution will notify Sterling IRB promptly in writing of any suspension, restriction, termination, or expiration of its FWA.

Institution agrees that Sterling IRB may include Institution's name in Sterling IRB's directory of institutions in which Sterling IRB provides IRB review services.

This document must be kept on file by both 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, emailed or faxed form.

This Agreement is effective as of the last date of signature below.

[Institution]	[Sterling IRB]
(Authorized Signature)	(Authorized Signature)
Name:	Name:
Title:	Title:
Date:	Date:

IRB Jurisdiction Form

This form is required for sites where IRB jurisdiction must be authorized or waived to Sterling IRB.

Protocol #:	**SIRB Official Use Only** **If an SIRB ID# has been assigned, list here:**
Sponsor:	
Principal Investigator:	
Name of Institution:	

Acknowledgement by Institution *(please select one box)*

☐ This institution maintains a Master Service Agreement with Sterling IRB, see the attached Institution Cover Page.
*(*Note: *This form is not required if an Institution Cover Page is provided with the submission)*

☐ This institution is a member of SMART IRB and has agreed to cede IRB review to Sterling IRB for the above-referenced protocol. IRB review will be ceded under the SMART IRB Master Common Reciprocal IRB Authorization Agreement.

☐ This institution requires a fully executed Authorization Agreement or other study-specific reliance agreement, see the attached form.
(Note: A template authorization agreement is available on our website, http://sterlingirb.com/forms.html)

☐ This institution maintains an institutional review board or human subjects committee, waives jurisdiction, and accepts the review services of Sterling IRB for the above-referenced protocol. This institution ☐ does / ☐ does not want to be copied on study related materials.

☐ This institution maintains no review board, waives jurisdiction, and accepts the review services of Sterling IRB for the above-referenced protocol. This institution ☐ does / ☐ does not want to be copied on study related materials.

{If your IRB/REB or HRPP wants to receive study related materials from Sterling IRB, please provide the contact name and email address for the individual(s) from the IRB/REB or HRPP. This individual will be granted access to SilverLink, Sterling IRB's secure web portal, to retrieve documents.}

Name: Phone: E-mail:

Name: Phone: E-mail:

I, the submitting party, attest that the Investigator named at the beginning of this form is authorized to conduct the above referenced study at this institution under the jurisdiction of Sterling Institutional Review Board and the information provided is accurate and submitted by, or under the authority of, the Principal Investigator.

NAME OF PERSON COMPLETING THIS FORM:

Printed Name: _____ Company and Position: _____

Phone Number: _____ E-mail Address: _____

INSTITUTIONAL REVIEW BOARD MASTER SERVICES AGREEMENT –
STERLING INSTITUTIONAL REVIEW BOARD AND [INSTITUTION NAME]

THIS INSTITUTIONAL REVIEW BOARD MASTER SERVICES AGREEMENT ("**Agreement**") is effective as of the date of the last signature hereto (the "**Effective Date**") by and between [INSTITUTION NAME] ("**INSTITUTION**"), with its principal place of business located at [INSTITUTION ADDRESS] and Sterling Independent Services, Inc. operating as Sterling Institutional Review Board, with its principal place of business located at 5500 Interstate North Parkway, Suite 515, Atlanta, Georgia, 30328 ("**STERLING**") (hereinafter individually referred to as the "**Party**" or together referred to as the "**Parties**").

WHEREAS, INSTITUTION desires to obtain institutional review board services for certain non-exempt human subjects research studies; and

WHEREAS, STERLING desires to provide such services upon the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Term

The term of this Agreement shall commence upon the Effective Date and shall continue until such time as either Party gives sixty (60) days written notice of termination.

2. IRB Services

STERLING shall provide institutional review board services ("**IRB Services**") as set forth in 21 CFR Parts 50 and 56, 45 CFR part 46 and International Conference on Harmonization Guideline for Good Clinical Practice (E6) Chapter 3 and any other applicable laws, rules or regulations which govern the rights and welfare of human subjects involved in research studies ("**Applicable Laws**").

The IRB Services provided by STERLING shall include, but not be limited to:

- review and approval or disapproval of new protocols;
- review and approval, disapproval or modification of consent forms or waivers of informed consent;
- review and approval of modifications to protocols;
- review and approval or disapproval of the investigator(s) and changes in research;
- collection of reports of unanticipated problems and serious or continuing noncompliance;
- maintenance of required IRB records pursuant to applicable federal regulations;
- continuing review of studies at intervals appropriate to the degree of risk, not less than annually.

STERLING shall promptly notify the currently-approved Principal Investigator ("**PI**") of any Covered Study of all IRB decisions and shall make available to the INSTITUTION, upon request, all relevant IRB records, including but not limited to minutes, approved consent documents, and other records that document the IRB's determinations.

STERLING will utilize independent discretion and judgment in providing IRB Services in a timely, professional and workmanlike manner in accordance with internationally accepted standards, and shall, at all times: (i) use individuals of suitable training and skill to perform its duties and

responsibilities under this Agreement; (ii) be in possession of all the necessary facilities, resources and personnel required to perform its duties and responsibilities under this Agreement; and (iii) comply with all Applicable Laws and STERING's standard operating procedures.

STERLING will maintain during the term of this Agreement all of the necessary licenses, permits and/or registrations to perform the IRB Services in accordance with the terms and conditions of this Agreement.

This Agreement covers INSTITUTION's studies involving human subject research that INSTITUTION submits to STERLING and requests STERLING to provide IRB services as the IRB of record ("**Covered Studies**").

STERLING shall notify the INSTITUTION promptly

- if there is ever a suspension or restriction of the IRB's authorization to review Covered Studies;
- of any changes in STERLING's operating procedures or practices that might affect the INSTITUTION's reliance on STERLING reviews;
- of complaints from human subjects enrolled in a Covered Study at INSTITUTION;
- of unanticipated problems involving risks to subjects or others in a Covered Study;
- if STERLING determines that serious or continuing non-compliance has occurred, and any steps that STERLING deems necessary for remediation of non-compliance;
- of suspension or termination of IRB approval of a Covered Study;
- of any communication with the FDA, OHRP or funding agency of matters relevant to human subject protections and relating to COVERED STUDIES; or
- of changes in accreditation status

Upon request, STERLING will perform those determinations required by the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA") with respect to the use and disclosure of Protected Health Information ("PHI") for research subject to this Agreement, including authorizations and waivers of authorization for the use and disclosure of PHI. If it becomes necessary for the parties to use or disclose PHI in any way not covered by the existing authorization or waiver of authorization, then the parties will work together to determine any additional steps necessary to ensure that the required information is used or disclosed in a HIPAA-compliant manner. It is expressly understood that, by providing review services as described herein, STERLING shall not be regarded as a "business associate" of the INSTITUTION as defined by HIPAA.

3. Compensation

STERLING will charge for IRB Services in accordance with its published fees in effect at the time that IRB Services are rendered. For new studies submitted to STERLING, STERLING shall bill INSTITUTION, investigators or sponsors, or their agents, for services rendered as directed upon the applicable submission form(s); provided, however, if STERLING 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 noted in the submission form(s).

The Parties acknowledge and agree that STERLING's fees represent fair and equitable compensation for the IRB Services provided. In no event shall compensation hereunder be intended to influence or guarantee STERLING's opinions, results, or decisions made in conjunction with the IRB Services.

4. Requests for IRB Services

The INSTITUTION contact ("**INSTITUTION Contact**") designated herein is authorized to request STERLING to perform IRB Services on behalf of INSTITUTION. The INSTITUTION Contact will request IRB Services for specific Covered Studies by submitting the Study materials accompanied by a written document specifying that INSTITUTION is requesting IRB Services under this Agreement.

5. 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, business associate 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.

6. Responsibilities of INSTITUTION

The INSTITUTION acknowledges and agrees to cooperate in STERLING's responsibility for initial and continuing review, record keeping and reporting. INSTITUTION shall, in a timely manner, provide information requested by STERLING in order to conduct its reviews. INSTITUTION will not approve any Covered Study that has been disapproved by STERLING. INSTITUTION may, however, disapprove any Covered Study approved by STERLING. INSTITUTION agrees to abide by the decisions of STERLING and shall use its best efforts to ensure that any Covered Study performed by INSTITUTION shall be conducted in accordance with those decisions.

INSTITUTION shall ensure that the investigators and other staff at INSTITUTION who are conducting Covered Studies are appropriately qualified and meet INSTITUTION'S standards for eligibility to conduct research. INSTITUTION shall ensure that investigators conducting Covered Studies at INSTITUTION receive proper initial and continuing education related to human subject protection.

INSTITUTION shall notify STERLING promptly:

- of any proposed changes to the research and ensure that such changes in approved research (including changes in the consent document) may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;
- if there is ever a suspension or restriction of the INSTITUTION's authorization or ability to conduct Covered Studies;
- of any local requirements or local research context issues relevant to STERLING's determination, prior to STERLING's review
- of any changes in institutional operating procedures or practices that might affect STERLING's ability to review for the INSTITUTION;
- of a significant complaint from a human subject enrolled in a Covered Study reviewed by STERLING;
- of unanticipated problems involving risks to subjects or others in a Covered Study;
- if the INSTITUTION believes that serious or continuing non-compliance has occurred in a study reviewed by STERLING, and any steps the INSTITUTION deems necessary for remediation of non-compliance;
- of suspension or termination of Institutional approval of a Covered Study;
- changes in accreditation status, if applicable.

The INSTITUTION will maintain all research records, including informed consent documents and HIPAA authorizations, in accordance with applicable federal, state, and local regulations.

INSITUTION shall cooperate with any STERLING investigation regarding serious or continuing noncompliance or an unanticipated problem involving risk to subjects or others related to a Covered Study at the INSTITUTION. Nothing in this Agreement shall prevent either party from conducting its own investigation. However, STERLING shall have primary authority to determine whether serious or continuing noncompliance or unanticipated problems involving risks to subjects or others have occurred.

If STERLING determines that it must report the findings of an investigation to the sponsor, OHRP, the FDA and/or other oversight entities, it will notify the INSTITUTION in advance. The party making the report will share the report with the other party before it is sent to the sponsor/oversight authority, and will copy the other parties' institutional official(s) and designees. However, nothing in this Agreement shall be construed to prevent either party from making its own report or making prompt reports in accordance with its written procedures.

The INSTITUTION may perform its own investigator conflict of interest analysis under its relevant policies. Any applicable conflict of interest and associated management plan shall be communicated to STERLING. STERLING will implement institutional conflict of interest management plans to the extent that they involve human subject protection considerations, such as mandated language in informed consent forms once this information is communicated to STERLING. STERLING retains the authority to impose additional prohibitions or conflict of interest management requirements more stringent or restrictive than proposed by the INSTITUTION if necessary to approve the research, provided, however, STERLING will not modify or change any management plan or mandated disclosure to subjects without informing the INSTITUTION and/or PI.

INSTITUTION shall ensure that the Clinical Trial Agreement (CTA), if any, and the consent form(s) for Covered Studies do not conflict with each other regarding the compensation for injury. INSTITUTION will inform STERLING of its procedures to resolve such conflicts upon request. 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 INSTITUTION and STERLING.

INSTITUTION agrees to notify STERLING of all communications to and from the FDA, OHRP and/or other applicable federal and state regulatory agencies regarding Covered Studies. INSTITUTION also agrees to notify STERLING of any related IRB matters concerning investigators who have submitted studies to STERLING for review.

INSTITUTION will notify STERLING of any research requiring STERLING's review, and will follow STERLING's standard submission requirements to initiate the review process and/or transfer studies to STERLING. Each Study shall be submitted to STERLING with an accompanying document referencing this Agreement as detailed in Section 4 of this Agreement. Investigators may use the IRB Jurisdiction Form or the parties may develop an Institution Cover Page to be submitted in lieu of the IRB Jurisdiction Form.

Where an investigator at INSTITUTION is conducting a Covered Study and acting as its sponsor or is providing information to STERLING on the sponsor's behalf, INSTITUTION shall ensure that submission materials indicate who will provide care for research-related injury, and who is responsible to pay for it.

Where an investigator at INSTITUTION is conducting a Covered Study and acting as its sponsor or is providing information to STERLING on the sponsor's behalf, INSTITUTION shall ensure that STERLING is promptly notified of any findings obtained from on-site monitoring activities or from study results obtained as part of a Covered Study or for two years after the Covered Study has closed that could affect the safety or medical care of a study participant or a study participant's willingness to continue participation in the Covered Study, influence the conduct of the Covered Study, affect the scientific design/integrity of the Covered Study, or alter STERLING's determination of whether or how the Covered Study should be conducted. This may include findings arising from study sites not under STERLING's review. STERLING will determine whether and how the reported information, or part of it, should be provided to study participants (including former participants, where appropriate) by the investigator or, in their absence, by the INSTITUTION and the INSTITUTION agrees to cooperate with STERLING in carrying out its determination.

7. <u>Confidential Information</u>

For purposes of this Agreement, the Party that transmits Information shall be referred to as the "Discloser," and the party to which Information is transmitted shall be referred to as the "Recipient." The term "Confidential Information" shall mean any and all information disclosed by the Discloser to the Recipient, or to any of its agents, affiliates, officers, directors, employees and subcontractors either in oral, written or any tangible form. Confidential Information includes, but is not limited to, technical, scientific, financial, strategic, marketing or product information; practices and processes; business systems and techniques; billing practices; computer processes, programs and codes; forms; and production processes.

Recipient shall hold in confidence any and all Confidential Information revealed by the Discloser or with which it became acquainted within the framework of this Agreement, and shall not use or disclose Confidential Information to any person or entity, except (i) to such of its own employees, independent contractors and representatives in the course of providing services hereunder (ii) to authorized agents of the federal government if required for audit or regulatory purposes, and (iii) to such other recipients as the Discloser may give prior written approval; provided, however, that recipients of Confidential Information shall have first executed a confidentiality and non-use agreement with the Recipient. Each Party further agrees that Confidential Information shall not be used except for the purpose of this Agreement as set forth herein.

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. Additionally, nothing in this Agreement shall restrict a Party from disclosing that STERLING reviews research for INSTITUTION.

The obligations of this Confidential Information section will not apply to any Confidential Information which the Recipient is able to demonstrate:

i) Was in its possession prior to being received from the Discloser and was not acquired, directly or indirectly, from the Discloser, or
ii) Was in the public domain, at the moment of being received from the Discloser, or
iii) Became part of the public domain through no fault of the Recipient, after having been so communicated, or
iv) Was lawfully received by the Recipient from some third party having a right of further disclosure, or
v) Is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by Recipient.

Each Party hereto is, and shall remain, the exclusive owner of its Confidential Information and all patents, copyright, trade secret, trademark and other intellectual property rights therein. No license or conveyance of any such rights is granted or implied under this Agreement.

The Parties agree that information exchanged under this Agreement, including Confidential Information, may be transmitted via facsimile or electronic mail, or sent via regular or express mail.

8. Termination

Notwithstanding the terms of Section 1 of this Agreement, 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. During the 30-day cure period, each Party will continue to perform its duties in accordance with this Agreement.

Notwithstanding the immediately preceding paragraph, the Parties specifically recognize that Applicable Laws require that an IRB conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. Therefore, termination of this Agreement shall not affect STERLING's obligations of continuing review for Covered Studies approved hereunder or INSTITUTION's payment responsibilities until such Covered Studies are transferred to and re-reviewed by another IRB or closed. If active Covered Studies are transferred to Institution's IRB or another IRB, an additional fee equal to STERLING's continuing review fee shall be charged to INSTITUTION for each active Covered Study transferred.

9. Indemnification

By INSTITUTION: INSTITUTION will indemnify, defend and hold harmless STERLING, its affiliates, and their officers, directors, agents and employees ("STERLING Indemnified Parties"), from and against any and all losses, damages, judgments, costs, awards, expenses (including reasonable attorneys' fees) and liabilities (collectively, "STERLING Parties Losses") arising out of a claim made or suit brought by a third party as a result of (i) the failure of INSTITUTION Indemnified Parties, or any of them, to comply with this Agreement or all Applicable Laws; (ii) the negligence or willful misconduct of INSTITUTION Indemnified Parties, or any of them; (iii) the administration of a study article to or testing of a study article on a patient or subject (or use of a study article by a patient or subject); and (iv) a personal injury to a subject in a research study resulting from the failure of INSTITUTION to disclose relevant information to STERLING; provided, however, that the amount of such indemnification obligation shall be reduced in each case to the extent that any such STERLING Parties Losses arise out of the negligence or willful misconduct of the STERLING Indemnified Parties, or any of them.

By STERLING. STERLING shall indemnify, defend and hold harmless INSTITUTION, its affiliates and their officers, directors, agents and employees ("INSTITUTION Indemnified Parties"), from and against any and all losses, damages, judgments, costs, awards, expenses (including reasonable attorneys' fees) and liabilities (collectively, "INSTITUTION Parties Losses") arising out of any claim made or suit brought by a third party as a result of (i) the failure of STERLING Indemnified Parties, or any of them, to comply with this Agreement or all Applicable Laws; and (ii) the negligence or willful misconduct of STERLING Indemnified Parties, or any of them; provided, however, that the amount of such indemnification obligation shall be reduced to the extent that any such INSTITUTION Parties Losses are caused by the negligence or willful misconduct of the INSTITUTION Indemnified Parties, or any of them.

Obligations of Indemnities. The Party seeking indemnity ("Indemnified Party") shall give the other Party ("Indemnifying Party") written notice within ten days of receiving a claim upon which such Indemnified Party intends to base a claim for indemnification (an "Indemnity Claim") under this Article. The Indemnified Party shall have the right to participate jointly with the Indemnifying Party, at its own expense, in the defense, settlement or other disposition of any Indemnity Claim. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the Indemnified Party becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to defend, settle or otherwise dispose of such Indemnity Claim, on such terms as the Indemnifying Party, in its sole and absolute discretion, shall deem appropriate, provided that the Indemnifying Party shall provide reasonable evidence of its ability to pay any damages claimed and with respect to any such settlement shall have obtained the written release of the Indemnified Party from the Indemnity Claim. The Indemnifying Party shall obtain the written consent of the Indemnified Party, which shall not be unreasonably withheld, prior to ceasing to defend, settling or otherwise disposing of any Indemnity Claim if, as a result thereof, the Indemnified Party would become subject to injunctive or other equitable relief or the business of the Indemnified Party would be adversely affected in any manner. INSTITUTION and STERLING agree to cooperate and will require INSTITUTION Indemnified Parties and STERLING Indemnified Parties to cooperate with the Indemnifying Party and its attorneys and insurers in the defense and disposition of an Indemnity Claim.

10. Limitation of Liability

EXCEPT WITH REGARD TO THE PARTIES' INDEMNIFICATION OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING IN CONNECTION WITH ANY DEFAULT OR BREACH OF OBLIGATIONS UNDER THIS AGREEMENT OR ANY ATTACHMENTS HERETO.

11. Miscellaneous

a. Each Party represents and warrants that it has and will maintain during the term of this Agreement, and for a period of two (2) years thereafter, insurance in the types and limits generally accepted in the industry and sufficient to cover its obligations hereunder, including indemnification obligations. Upon written request, either Party shall provide the other with a copy of its certificate(s) of insurance demonstrating this coverage.

b. STERLING maintains a secure electronic portal ("SilverLink") accessible via the internet. STERLING receives submission documents and posts IRB documents via SilverLink. INSTITUTION acknowledges that it is INSTITUTION's obligation to notify STERLING when the access of an INSTITUTION employee or agent should be disabled for any reason.

c. By agreeing to the terms and conditions of this Agreement, Parties represent that they are not in violation of any terms and conditions of any agreement with any other individual or entity.

d. This Agreement shall be construed in accordance with the laws of the State of Georgia without regard to its conflict of laws provisions.

e. This Agreement may be modified only by a writing signed by the parties hereto.

f. If any provision of this Agreement conflicts with the law under which this Agreement is to be construed or if any such provision is held invalid by a court, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with Applicable Law and the remainder of this Agreement shall remain in full force and effect.

g. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their successors and assigns; provided, however, that INSTITUTION shall not have the right to transfer or assign this Agreement or to assign any rights thereunder or delegate any of the obligations thereunder without the prior written consent of STERLING. Any unauthorized attempt to assign or delegate any portion of this Agreement by INSTITUTION shall be void. STERLING may assign this Agreement to an affiliate or successor upon written notice to INSTITUTION, in which case INSTITUTION agrees to release and forever discharge STERLING from any and all claims that may arise out of this Agreement after the effective date of such assignment.

h. Forbearance by either Party with respect to a breach of any provision of this Agreement shall not be deemed to constitute a waiver with respect to that provision or excuse a similar subsequent breach of any provision hereof.

i. Any notice required or permitted to be given hereunder by either Party hereto shall be in writing and shall be deemed given on the date received if delivered personally, by recognized overnight courier, by email, or by facsimile, or five (5) days after the date postmarked if sent by registered or certified U.S. mail, return receipt requested postage prepaid, to the following address:

If to INSTITUTION, INSTITUTION Contact:	**If to IRB:**
[INSTITUTION CONTACT NAME] [TITLE] [ADDRESS] [PHONE] [FAX] [EMAIL]	Kathye Richards, CIP Vice President of Client Services Sterling Institutional Review Board 6300 Powers Ferry Road Suite 600-351 Atlanta, GA 30339 Phone: (888) 636-1062 Fax: (770) 690-9492 Kathye.Richards@SterlingIRB.com

Either Party may change its notice address and contact person by giving notice of same in the manner herein provided.

j. No default, delay or failure to perform on the part of either Party shall be considered a default, delay or failure to perform an obligation under the Agreement if such default, delay or failure to perform is due to causes beyond either Party's reasonable control including, but not limited to, acts of God, fire, earthquake, government action, inactions of governmental authorities, weather, disease, war, insurrection, civil strife, riots or power failure (a "Force Majeure Event") provided that the affected Party exercises all reasonable efforts to eliminate the effects of the Force Majeure Event on this Agreement as soon as and to the extent practicable. 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. Notwithstanding the foregoing, this provision

does not limit or alter a Party's right to terminate this Agreement as set forth herein.

k. 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.

l. This Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements, whether written or oral. This Agreement shall be construed according to its fair meaning and not strictly for or against any Party.

m. This Agreement does not preclude any party from participating in any other IRB authorization agreement that it may have or enter into with other entities for research not covered by this Agreement.

12. Survival

The obligations of the parties contained in Sections 3, 7, 9, 10, 11 and 12 herein shall survive termination of this Agreement.

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Agreement as of the Effective Date.

Sterling Independent Services, Inc.	[INSTITUTION]
_____	_____
(Authorized Signature)	(Authorized Signature)
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____