Annotated with UNC-specific responses

SCHULMAN ASSOCIATES IRB

Research Site Submission Form

SECTION 1.0: Submission Instructions & Requirements

1. Standard research site submission requirements:

- Completed *Research Site Submission Form*
- *Curriculum vitae* (CV) of the Principal/Qualified Investigator (PI/QI) and each Sub-Investigator (Sub-I), if not already on file
- Clinical Research Budget Template (Canada sites only) TCPS 2 Article 11.11
- Copy of the PI/QI's current medical/professional license (Canada, Mississippi and Puerto Rico sites only)

NOTE: Please visit www.sairb.com for submission requirements for Non-Interventional, Federally Funded/FWA and Transfer of IRB Oversight studies.

2. Submission instructions: Submit via Secure eSubmission, email to Submissions@sairb.com or fax to (866) 596-1535.

SECTION 2.0: General Information

1. Sponsor: _____ **2. Protocol Number:** _____ **3. Indication:** _____

4. Investigator and Primary Site Information:

>>> Enter information as it should appear on all IRB correspondence, including the Informed Consent (IC).

PI/QI Name (including degree & credentials): _____

Office Phone Number to appear on IC (Optional): _____

24-Hour Phone Number to appear on IC (Required): _____

Site Name: _____ Address: _____ City: _____

State/Province: _____ Zip/Postal Code: _____ Country: _____

Site Phone: _____ Fax: _____ Email: _____

5. Will this study be conducted at additional locations under the same PI/QI listed above?

☐ No

☐ Yes **>>> a.** Please provide the names and addresses of these additional locations (attach additional sheets if necessary): _____

b. Please specify which of these additional locations are to be listed on the Informed Consent (attach additional sheets if necessary): _____

NOTE: Schulman is **not** able to review/approve research in: Alberta, Saskatchewan and Newfoundland and Labrador. Schulman will only review research in Québec that involves adults with capacity to consent.

6. Is this research site under the jurisdiction of the Capital District Health Authority of Nova Scotia?

☐ No

☐ Yes **>>>** Schulman is not able to review research located in the 'Capital District Health Authority'.

7. Will this study be conducted through an institution that has a contract for Schulman review services?

"Institutions" include academic medical centers, colleges, universities, hospital systems, community hospitals, nursing facilities, public health clinics, and other centers that may or may not have local IRBs. Please visit the Institution portion of the Schulman website for more information.

☐ No

☐ Yes **>>>** Please provide the name of the institution identified on the contract or agreement: _____

SECTION 3.0: Contact Information

1. Site Contact Information: ☐ **Check here if same as Primary Site Information listed in Section 2.0.**

Name: _____ Title: _____ Email: _____

Phone: _____ Fax: _____ Mailstop: _____

Company: _____ Address: _____ City: _____

State/Province: _____ Zip/Postal Code: _____ Country: _____

2. Site Correspondence Information: ☐ **Check here if same as Site Contact Information listed above.**

Name: _____ Title: _____ Email: _____

Phone: _____ Fax: _____ Mailstop: _____

Company: _____ Address: _____ City: _____

State/Province: _____ Zip/Postal Code: _____ Country: _____

SCHULMAN
ASSOCIATES IRB

Research Site Submission Form

Leave blank unless your department administrator requests access

3. Institution Contact Information (only if applicable):

Name:		Title:		Email:	
Phone:		Fax:		Mailstop:	
Company:		Address:		City:	
State/Province:		Zip/Postal Code:		Country:	

NOTE: Schulman site contacts listed on this form will receive SiteAccess 1.0 to review status information and receive IRB documents. Please visit the SiteAccess 1.0 login page to request access for an additional user.

SECTION 4.0: FWA & Previous Review

1. Is this study being conducted under a Federalwide Assurance (FWA)?

☒ No

☐ Yes >>> Please provide the FWA number: _____

Select "NO"

NOTE: Please refer to Federally Funded/FWA Site for additional submission requirements.

2. Was this site previously submitted to another IRB/REB for this protocol?

☒ No

☐ Yes >>> Please complete **a.** and **b.**:

Select "NO". Although you were required to submit your study to the UNC IRB, the UNC IRB is reviewing to confirm compliance with institutional requirements only.

a. Was it disapproved or withdrawn?

☐ No

☐ Yes >>> Please attach a detailed explanation.

b. Are you requesting transfer of IRB oversight?

☐ No

☐ Yes >>> Please refer to Transfer of IRB Oversight Site for additional submission requirements.

SECTION 5.0: Research Site Information

1. Where will the study be conducted? Check all that apply:

☐ Research Facility	☐ Private Practice	☐ Public Health Clinic
☒ Hospital or Hospital System	☐ Surgery Center	☐ Free-standing Psychiatric Facility
☒ University/Academic Medical Center	☐ Nursing Care Facility	☐ Facility owned by or affiliated with a hospital or university
☐ Hospice	☐ Other: _____	

Mark locations where research will be conducted, including other off site clinics owned by the Hospital if relevant to your site

2. Will any part of this study be conducted in a facility under the jurisdiction of or affiliated with another IRB?

☐ No

☒ Yes >>> Please submit a **Letter of Deferral** from that institution, signed by the CEO of the institution or Board Chairperson, authorizing Schulman to be the reviewing IRB/REB. Please reference the Letter of Deferral. If you will use an outside hospital to perform a study related procedure, but no subjects will be consented and no study drug will be administered at the hospital, please reference the Hospital Procedure Letter as a template for composing a hospital procedure letter to be included with your submission.

3. Approximately how many research studies have been conducted at this site during the last calendar year? _____

4. Please describe the attitudes in your community (*e.g., religious, ethical, ethnic or economic*) that affect the conduct of research at your site as:

☐ Positive ☐ Neutral ☐ Negative >>> Please attach an explanation.

5. What precautions are used to maintain confidentiality and security of study records at your site? Check all that apply:

☐ Paper-based records will be kept in a secure location and will be accessible only to personnel involved in this study;

☐ Computer-based files will be available only to personnel involved in the study through the use of access privileges and passwords;

☐ Prior to accessing any study-related information, site personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable health information;

☐ Whenever feasible, identifiers will be removed from study-related information; and/or

☐ Other (specify): _____

Mark "yes" and upload a copy of UNC Permission letter

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6. What precautions are used to maintain the privacy of subjects at your site? Check all that apply:

☐ A private room for discussion of health-related information;
☐ Working knowledge of and adherence to the HIPAA Privacy Rule / Final Omnibus Rule (US) or PIPEDA (Canada);
☐ Consideration of parental inclusion in the visit if the study involves children;
☐ Consideration of parental absence in the visit if the study involves teens; and/or
☐ Other (specify): _____

7. Are there any state, provincial or local laws that govern the conduct of research (*e.g., California Experimental Subjects' Bill of Rights*) at your site?

☐ No
☒ Yes >>> Please attach an explanation.

Upload a copy of document entitled "NC State Laws Governing Clinical Research" (provided in the General Documents folder)

NOTE: If unsure, please contact a healthcare attorney or your local, state or provincial government.

8. What resources are available at your site for a subject in need of emergency care? Check all that apply:

☐ ACLS trained personnel and crash cart with emergency medications
☐ Automatic external defibrillator
☐ On-site paramedics
☐ Other (please specify): _____
☐ Access to 911
☐ CPR certified staff
☐ N/A

9. Please provide the travel time between the research site and the nearest hospital: __

10. Do you plan to enroll subjects through a legally authorized representative (LAR)?

☐ No
☐ *Yes >>> Please complete **a.** through **c.**:

If you will use a legally authorized representative, upload a copy of the "LAR Guidance" document (provided in General Documents folder)

*An LAR may consent on behalf of a subject ONLY if the Board has determined that an LAR is appropriate for the study.

a. Which individuals will you allow to give consent/permission? For example, durable power of attorney for health care, spouse, guardian etc.: _____

b. How will you verify who constitutes an LAR in your state/province? Check all that apply:

☐ Legal Counsel ☐ Sponsor/CRO ☐ Other: _____

NOTE: Who can serve as a legally authorized representative (LAR) is determined on a state-by-state/province-by-province basis. When a study requires consent to be provided by an LAR, Schulman requests that the PI/QI confirm with a regulatory attorney or with the sponsor/CRO who may serve as an LAR for their particular state/province. The sponsor is responsible for ensuring proper monitoring of investigators under 21 CFR Part 312.50 or Part C Division 5 of the Canadian Food and Drug Regulations C.05.010, which includes confirming that a legally effective consent process was performed. The monitor should verify that the person signing as LAR has the authority to provide consent on the subject's behalf; otherwise the consent may not be legally effective.

c. Briefly describe the plan to assess the subject's ability to be able to provide consent and/or assent (attach additional sheets if necessary): _____

11. Massachusetts sites conducting investigational drug studies ONLY: Are you registered with the Massachusetts Department of Public Health to dispense investigational drugs?

NOTE: You may contact the Massachusetts Department of Public Health.

☐ No >>> Please obtain the appropriate registration in order to conduct research in the state of Massachusetts.
☐ Yes >>> Please attach a copy of your current registration document.

12. Is this research site a "covered entity" under the HIPAA Privacy Rule/Final Omnibus Rule (US only)?

☐ No
☒ Yes

SECTION 6.0: Research Experience, Education & Training

1. Please list the PI/QI and all Sub-Is for this study and indicate the clinical research experience (in years) and the human research subject protection education and training for each: (Please attach additional sheets if necessary to list all Sub-Is)

Name (First Last), Degree	Research Experience	Education & Training
PI/QI: _____	____ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☒ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____

All investigators & study staff required to take CITI ethics ("IRB") modules

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Sub-I: _____	____ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☐ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: _____	____ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☐ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: _____	____ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☐ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____

SECTION 7.0: Informed Consent

1. Will compensation for study participation or reimbursement for expenses be provided?

☐ No

☐ Yes >>> Please detail the compensation/reimbursement plan to be included in the IC by completing **a.** through **c.**:

a. Who will receive compensation/reimbursement? Check all that apply:

☐ Adult Subjects ☐ Minor Subjects ☐ Parents/Guardians of Minor Subjects ☐ Caregivers ☐ Other: _____

b. Please attach the established visit payment schedule or list the payment amount for each visit in the spaces provided below.

NOTE: To avoid delays in processing, please refer to the visit schedule in the study protocol to ensure all visits are addressed**.**

Payment of $_____ for _____ visit
Payment of $_____ for _____ visit
Payment of $_____ for _____ visit
Payment of $_____ for _____ visit
Payment of $_____ for _____ visit

Examples of visit types that should be addressed:

- Screening
- Completed
- Inpatient/Confinement
- Telephone
- Unscheduled
- Optional
- Sub-study
- Subjects serving as alternates

>>Please list all visits for which subjects will **NOT** be compensated/reimbursed: _____

>>Would you like the payment total to be listed in the Informed Consent?

☐ No

☒ Yes >>> Please provide the **Total** payment of up to $_____ for **completing** all study visits.

c. When will compensation/reimbursement be provided? Choose one:

☐ after each visit
☐ weekly
☐ bi-weekly (every 2 weeks)
☐ monthly
☐ annually
☐ at the time participation in the study ends*
☐ at the end of the study*
☐ other: _____

***NOTE:** Compensation/reimbursement must be prorated across study visits and provided at least annually for participation lasting longer than 1 year.

2. Do you plan to consent/enroll non-English speaking subjects?

☐ No

☐ Yes >>> Please complete **a.** and **b.**:

a. What language(s) are necessary for IC translation(s)? Check all that apply:

☐ Spanish ☐ Canadian French ☐ Other: _____

b. Is there someone at your site fluent in the language(s) of the non-English speaking subject(s) who is capable of explaining the study and answering questions throughout the participation in the study (i.e. employee, member of the study staff, professional [impartial] translator)?

☐ No >>> Please attach an explanation.

☐ Yes

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NOTE: Translated study documents may be used only if enrollment of non-English speaking subjects is permitted by the protocol and authorized by the sponsor/CRO. All translations of study documents and materials approved in English must be approved by Schulman. You must comply with the safeguards pertaining to enrollment of subjects from the vulnerable group of non-English speaking subjects.
For further information, please reference the *Translations Guidance*.

3. Will your site participate in any current sub-studies of this protocol?

☐ No sub-studies exist or not participating in any sub-studies at this time

☐ Yes **>>>** Please attach list.

4. It is Schulman's expectation that the PI/QI will be aware of and comply with state/provincial laws and/or regulations regarding HIV testing when HIV testing is explicitly required by the protocol or when the protocol allows for HIV testing at the Investigator's discretion. Please confirm the PI/QI's agreement to follow this expectation:

☐ By checking here, you confirm that the PI/QI agrees that this site will comply with state/provincial laws and/or regulations pertaining to HIV testing, which may include, but may not be limited to obtaining informed consent, providing HIV counseling, and reporting positive HIV test results to public health authorities.

NOTE: Schulman recommends that Canadian sites consult with their provinces' health officials and/or legal counsel to assist in determining the provinces' laws and/or regulations pertaining to HIV testing. Schulman recommends that US sites consult with their states' departments of health and/or legal counsel to assist in determining the states' laws and/or regulations pertaining to HIV testing.

5. Which individuals at your site are authorized to conduct the informed consent discussion with subjects?

☐ PI/QI ☐ Sub-Is ☐ Research Coordinator/Study Nurse ☐ Other: _____

6. What education related to informed consent discussion has been provided to these individuals?

☐ Job orientation ☐ In-house education ☐ Education provided by a professional association

☐ Role play ☐ Education provided by the sponsor/CRO ☐ Knowledge of protocol ☐ Other: _____

7. Please confirm the following regarding the informed consent process that will be followed for this study by checking the boxes below:

☐ Informed consent discussions with subjects will take place in a private area.

☐ Potential subjects will be allowed as long as needed to review the IC to decide study participation, including at home or overnight.

☐ The PI/QI will be available to answer subject questions during the informed consent process.

☐ A copy of the signed IC will be provided to the subjects.

☐ Information during the consent process will be provided in a language understandable to the subjects.

☐ Subjects will be informed of alternative treatments, therapies, or procedures prior to participation in this research study.

☐ No information will be presented to a subject that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the organization, or its agents from liability for negligence.

☐ Subject understanding of the study will be assessed following the consenting process and before being enrolled into the study.

☐ Coercion and undue influence will be minimized by: not allowing bonuses for study staff that are directly based on enrollment; providing compensation for participation/reimbursement for expenses that is based only on time and inconvenience to subjects; equitably prorating compensation for participation; thoroughly explaining the IC and allowing for subjects to ask questions; and implementing appropriate safeguards for vulnerable subjects.

NOTE: If any of the above is not true for the consenting process at your site, please attach or provide a written explanation. _____

8. Will you be incorporating site-specific language, other than the compensation/reimbursement section and site contact information, into the consent form template developed by the sponsor and the Board?

☐ N/A **>>>** This study meets one of the following: 1) a single site study, and therefore does not have an informed consent form template developed by the sponsor and the Board; or 2) study does not involve a consent fo

☐ No **>>>** Schulman will incorporate your site-specific contact information and compensation/reimburse other site-specific language will be included under this option.

☒ Yes **>>>** Please complete **a.** through **b.**:

a. I am including in this submission (check one):

☒ The site-specific information in a tracked changed version of the consent form template.

☒ The site-specific information as a supplement document to this form for inclusion in the inform

☐ N/A; the site-specific information is on file with Schulman.

b. Has the sponsor provided approval of the site-specific language in the IC?

☐ No **>>>** Please obtain sponsor approval and attach written documentation. Failure to do so m review of your submission.

☐ Yes **>>>** Please attach written sponsor documentation. Failure to do so may result in a delay submission.

Changes should include UNC subject injury and COI language. See IRB permission letter and COI Finalization Letter (email) for details on changes to make. Also, remove HIPAA language as UNC will approve a separate HIPAA authorization form (as detailed in UNC permission letter).

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SECTION 8.0: Subject Recruitment Information

1. From what groups may subjects for this study be recruited? ☐ N/A – Extension Study

a. Gender:	☐ Male	☐ Female	
b. Economic Status:	☐ Upper Income	☐ Middle Income	☐ Lower Income
c. Ethnic Background:	☐ Caucasian	☐ African	☐ Asian
	☐ Hispanic	☐ Native American/Aboriginal	☐ Other: _____

2. If a potential subject is eligible for multiple research studies being conducted at your site, it is Schulman's expectation that both the PI/QI and the potential subject will collaborate to decide in which study the subject will enroll. Please check the appropriate response:

☐ By checking here, you confirm that the PI/QI agrees that the potential subject and study doctor will be involved in the decision.

☐ N/A; our research site does not perform competing research studies.

3. It is Schulman's expectation that referral fees (finders' fees) will not be paid to physicians/healthcare providers or others for referrals of research subjects in this study. Please confirm the PI/QI's agreement to follow this expectation:

☐ By checking here, you confirm that the PI/QI agrees that this site will not pay referral fees (finders' fees) for referrals of research subjects to this study without Board approval.

NOTE: Schulman agrees with the American Medical Association Code of Ethics – Section 6.03 & Canadian Medical Association – Policy 13.

SECTION 9.0: Vulnerable Groups

1. If your site plans to recruit or enroll subjects into this study from vulnerable groups, please check all applicable vulnerable groups below and review the provided safeguards:

Vulnerable Group	Safeguards
☐ **None**	No plans to recruit or enroll any vulnerable subjects; OR
☐ **Children**	Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. A child's parent or legal guardian must accompany a child during the informed consent process. A written assent should be prepared for children 7 years or older unless assent is waived by the Board. The child should be given an opportunity to decide, independently, whether or not to participate in the study. If the child agrees, his/her signature (or printed name) indicates assent. In Alabama, Nebraska, British Columbia, New Brunswick, Northwest Territories, Nova Scotia, Nunavut, and Yukon, persons younger than **19** are considered children. In Puerto Rico, persons younger than **21** are considered children. Schulman does not review studies that target wards of the state/province.
☐ **Economically Disadvantaged**	The site must ensure that the compensation is not presented in a manner that may be coercive. Payment must not be contingent upon completion of the entire study. There must be a plan to pro-rate payments. Any compensation or bonus for completion must be reasonable and not so large as to induce subjects to enroll or stay in the study.
☐ **Educationally Disadvantaged**	For an individual who may have trouble comprehending the written IC, the person conducting the consent discussion must review each section of the IC with the potential subject and pose questions after each section to ensure an adequate understanding. For an illiterate subject, an independent witness must also be present during the presentation of and signing of the IC. An independent witness must not be an employee of the investigator or research site.
☐ **Employees**	Measures must be taken to ensure the confidentiality of an employee's study-related medical records. Additionally, no action can be taken against an employee based on information to which an employer would not otherwise be entitled but obtains because of an employee's participation in a study. An employee who participates in a research study must be treated as other subjects and must be able to decide not to participate or to discontinue study participation without any impact on his/her employment status. The Board requires that each employee sign a non-coercion addendum prior to the subject's participation in the study. "Employee" refers to either an employee or an employee's family member who is participating in a research study.
☐ **Physically Impaired**	An individual with a physical impairment(s) (e.g., visual, hearing, speech) that would prevent normal communication, and who is unable to read and/or sign the IC, must have an independent witness present during the presentation and signing of the IC. The independent witness must also sign the IC. An independent witness must not be an employee of the investigator or research site.
☐ **Life-Threatening Condition / Seriously Debilitating Illness**	For an individual with a life-threatening condition the investigator must fully explain alternative treatments and that participation in a research study may not benefit his/her present medical condition. The investigator must confirm that the subject understands this information.

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☐ **Mentally Disabled/Cognitively Impaired**	An individual who is not competent to understand verbal and written information and provide informed consent must have an LAR. The law of the state/province where the site is located defines who may act as an LAR. The LAR must sign the IC on behalf of the subject. If checked, please attach, on a separate page, justification for inclusion into the study and explain how lack of capacity to consent will be determined. Please consult your state/province law regarding informed consent and LAR. **NOTE Canadian sites:** Schulman will only review research in Québec that involves adults with capacity to consent.
☐ **Non-English Speaking Subjects**	If the site consents a non-English speaking subject, it must use an IRB approved translated informed consent. The site must also provide someone (i.e.: Employee, member of the study staff, or impartial translator) who is capable of explaining the study and answering questions in the language of the non-English speaking subject throughout the subjects participation in the study. This person cannot be a family member or friend of the subject.
☐ **Nursing Home Residents**	Each state/province has a "Nursing Home Bill of Rights" of which the PI/QI, study staff, subject and LAR, if appropriate, must be fully aware.
☐ **Pregnant Women**	A pregnant woman must be fully informed regarding the foreseeable impact of the research on the fetus or resultant child. In addition, the individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy and will have no part in determining the viability of the fetus. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
Prisoners	Schulman does not review studies in which prisoners are the targeted population.
NOTE: Please attach: 1) a description of any additional safeguard(s) used at your site; and/or 2) a description of any additional vulnerable groups from which you plan to recruit and enroll and any additional safeguard(s) used to protect them.	

SECTION 10.0: Financial Interest

It is the policy of Schulman to require each **investigator*** who submits research studies for review and oversight to disclose any of the following **financial interests** when those financial interests are **related to the research**.**.

***Investigator:** As used in this policy, this includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.

****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested.

1. During the past calendar year, has any investigator involved in this study:

- Been an officer, director or employee of the sponsor of this research study?;
- Held ownership interest (equity or stock options) related to the research in excess of $5,000 when ref prices (if the sponsor is a publicly traded company) or other measure of fair market value and when a immediate family?;
- Held ownership interest (equity or stock options) related to the research whose value when aggregate represents 5% or more interest in any one single entity?;
- Held ownership interest (equity or stock options) related to the research of any value held in a non-pu
- Had any proprietary interest related to the research? (A proprietary interest is defined as property or including, but not limited to, a patent, trademark, copyright or licensing agreement.);
- Received, or made any arrangement to receive, any significant payments of other sorts related to the activities of the investigator? (A significant payment of other sorts is defined as: **(i)** payments by the activities of the investigator that have a monetary value of more than $5,000 exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.);
- Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?; OR
- Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.)

☐ No

☐ Yes **>>>** Please complete and attach the *Investigator Conflict of Interest Form*.

All members of the research team (as noted above) who whom a YES response is indicated for any of the questions listed in this section, must complete the Schulman COI form **IN ADDITION TO** completing any COI disclosures required by UNC-CH.

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SECTION 11.0: Regulatory History

1. Has this site and/or any investigator associated with this study been audited by the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Health Products and Food Branch Inspectorate (HPFB) or Environmental Protection Agency (EPA) within the last five (5) years?

☐ No

☐ Yes **>>>** Please complete **a.** and **b.**:

a. Please provide the name of the agency (FDA, OHRP, HPFB, EPA), name of each physician/investigator who was audited, and the date(s) of the audit(s):

Agency: _____ Physician/Investigator: _____ Date: _____

Agency: _____ Physician/Investigator: _____ Date: _____

b. Schulman must be in receipt of all audit-related correspondence including, but not limited to, the FDA Form 483, the Establishment Inspection Report (EIR), HPFB Inspection Letter and the response, if any, to all of the audits listed, unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Will submit when available

2. Are there state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

3. Since your last submission to Schulman, or if this is your first submission to Schulman, has any investigator involved with this study:

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?
- Had the FDA, OHRP, or EPA (US sites) or HPFB (Canadian sites) terminate a study?
- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g., suspension, revocation, or restriction?
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?
- Been convicted or charged with a crime (misdemeanor or felony)?
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents or provide an explanation. _____

SECTION 12.0: Investigator Certification & Signature

On behalf of all the investigators involved in this study, and under penalty of law, I certify that:

1. My signature below indicates that I will fulfill my responsibilities as Principal/Qualified Investigator as defined by the applicable federal, state, provincial and local law, ICH GCP guidelines and any additional responsibilities that may be imposed by Schulman IRB;
2. I will report to Schulman all Unanticipated Problems Involving Risks to Human Subjects or Others ("Unanticipated Problems") and Unanticipated Adverse Device Effects (UADEs) within ten (10) business days of discovery, and within twenty-four (24) hours of discovery if the Unanticipated Problem or UADE involves a death;
3. If applicable, I will report to Schulman all noncompliance issues that have an adverse effect on the safety or welfare of the study subject(s), and/or on the data collected, and/or are related to a breach of confidentiality within ten (10) days of discovery;
4. I will not make any changes in the research prior to receiving Board approval from Schulman unless an immediate change is necessary to eliminate an apparent hazard to the subjects and I agree to report to the Board within ten (10) business days any change to research that is necessary for subject safety that was implemented without Board approval;
5. I will report to the sponsor and Schulman any change of the location at which the study is conducted;
6. I will report to the sponsor and Schulman any proposed transfer of subject(s);
7. I, or someone under my supervision, will verbally explain the elements of informed consent to each potential subject or, if applicable, the subject's legally authorized representative before obtaining his/her signature on the informed consent;
8. The selection of subjects for this study will be equitable;
9. I am aware of my investigator responsibilities as set forth on the Schulman Associates Institutional Review Board, Inc. website www.sairb.com;

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10. Responses to the conflict of interest questions are accurate and complete and constitute a full disclosure of any conflicting interests and activities of any investigator or clinical research coordinator involved in this research at this site. I have discussed with these individuals the requirements to disclose any potential conflict of interest. I will disclose to Schulman any conflicts of interest that arise during the course of the study;

11. I have reviewed the information regarding safeguards for vulnerable group(s) and, for categories indicated in this form, I agree to the appropriate safeguards;

12. All study personnel have been made aware of the information provided to Schulman in this form;

13. No subject related study activities will occur prior to receiving the approval letter and informed consent from Schulman;

14. I will maintain a list of appropriately qualified persons to whom I have delegated significant clinical trial-related duties;

15. I will ensure adequate control of investigational drugs and devices, or products so that they are used only in approved research protocols and under the direction of approved researchers;

16. The protocol, clinical trial agreement or other contract with the sponsor/CRO of this study states: the responsible party who will provide medical care in case of study-related injury and who will pay for the care (e.g., sponsor, site, subject, insurance provider); the sponsor/CRO is required to promptly report to me any findings of study monitors that could affect the safety of participants or influence the conduct of the study, and I will promptly forward this information to Schulman; the sponsor/CRO is required to send routine and urgent data and safety monitoring reports to me, and I will promptly forward this information to Schulman; and the sponsor/CRO is required to report to me any study results uncovered within two (2) years of study closure that could directly affect subject safety, and I will promptly forward this information to Schulman; and

17. I have reviewed all responses provided in this *Research Site Submission Form* and that all responses are true and accurate. By submitting this form, I am confirming that I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI and the PI/QI has reviewed the submission form and agrees this information is true and accurate.

Principal Investigator [US]/Qualified Investigator [CAN] or Designee Signature	Signature Date (mm/dd/yyyy)
Principal Investigator [US]/Qualified Investigator [CAN] or Designee Name & Title	

Where a signature is required, please scan the signature page of the document into PDF format before submitting it electronically. If you are unable to scan the signature page into PDF format, you may fax it to Schulman at 866.596.1535.