Date: Monday, November 16, 2020 11:32:44 AM Print Close

SSU00071153 View: Investigator Application Lead In

Lead In / Confirmation Page

* To confirm you have accessed the correct form, please select one:

- (●) **I am a clinical research site that is joining a multi-site study for which Advarra IRB will act as the central IRB. The Sponsor or CRO has or will submit the protocol.**
- ( ) I am a clinical research site, institution, academic medical center, hospital, government agency, non-profit organization, or contractor/CRO that is submitting a single investigator study.
- ( ) I am a pharmaceutical Sponsor or CRO who will be conducting a multi-site study for which Advarra IRB will act as the Central IRB. I am submitting the protocol on behalf of all sites.

SSU00071153 View: Start of Investigator Application

Start of Investigator Application

1	* Please click **'Select'** to choose your Investigator:Betsy Casillo (Institution) *Note: If you **do not** see the Investigator listed, then you will need to create an account/register the person. To create an account/register the PI, you will need to exit out of the application, logoff, and go to the CIRBI home page and click on the Sign Up link*
2	* Full Protocol Title: New add on site submission example pre-submission * Protocol Number: New add on site submission example pre submission DO NOT DELETE

SSU00071153

View: Investigational/Research Location(s) and Subject Recruitment

Investigational/Research Location(s) and Subject Recruitment

1

* Do you want to submit sub-investigator/co-investigator information for IRB review (note: this is **not** an IRB requirement)

○ Yes ● **No**

2

Please add any other members that will need access to this study:

Name	Email	Role	Has Editing Privileges	Will Get Copied on Emails

No Team members entered

3

* Select the investigational/research location(s) this study will use, or click 'Add' to enter data if it is not shown below. If you need to make an Update to a location, select the location first and you will then be able to do an Update:

Add

		Company Name	Address
☐		CARRIE TEST	12, 12, mesa, AZ, 85212, USA
☐		null	null
☐		Demonstration	Demonstration, Demonstration, MD, 1234, USA
☑	Update	test 2	123 Main Street, Suite 200, Columbia, MD, 21045, USA
☐		Pain Centers of NC	7859 Center Street, Charleston, NC, 85290, USA
☐		test	123 Main Street, Suite 200, Columbia, MD, 21045, USA
☐		org 2	124 Main, O, AL, 21047, USA
☐		null	null
☐		org	123 Main St., Baltimore, MD, 21225, USA
☐		null	null

	Company Name	Address
☑ Update	Pain Centers of MD	2345 Liberty Road, Suite 250, Reisterstown, MD, 21127, USA

4

* Which of the following subject populations may be enrolled in this study?

- ☑ **Adults**
- ☐ Males Only (No Females)
- ☐ Females Only (No Males)
- ☐ Pregnant Women, Human Fetuses, or Neonates
- ☐ Minors (subjects under the age of majority)
- ☐ Prisoners
- ☐ Institutional/Nursing Home
- ☐ Hospitalized
- ☐ Potentially Decisionally Impaired/Cognitively Impaired/Mentally Ill Adults
- ☐ Economically Disadvantaged
- ☐ Educationally Disadvantaged/Individuals with Limited or No Reading Skills
- ☐ HIV Positive
- ☐ Terminally Ill
- ☐ Employees/Colleagues
- ☐ Students of Researcher
- ☐ Blind/Visually Impaired
- ☐ Non-English Speakers
- ☐ Healthy Subjects
- ☐ Military Personnel
- ☐ Other

If Other, please specify:

* Please confirm you are **not** targeting any population for enrollment other than those required by the study design (inclusion criteria)

● **I confirm**

○ I do not confirm***

If you selected 'I do not confirm' above, please provide specifics here:

5

* How many subjects are expected to be enrolled at your site(s): 24

6

If the Sponsor has assigned you a Site # for this study, please provide it here *(if there is no site #, please proceed)*

7

* As part of this study, are you participating in a network (e.g. TDN, SIREN, etc.)? ● **Yes** ○ No

* Please provide the name of the network:Betsy Network

Date Submitted:

SSU00071153 View: Multiple Investigational/Research Location Questions

Multiple Investigational/Research Location Questions

1

Because you have indicated that subjects may be seen at more than one location, respond to the following questions:

* How often will the PI communicate with the research staff at each location?
Daily

If Other, specify:

2

* Choose all the methods that the PI and the research staff will use to communicate:

Telephone

If Other, specify:

3

* Are any of your locations a nursing home/care facility, school, or facility where the subject may be a student or resident? ○ Yes ● **No**

If yes, has the facility documented in writing that they will allow this research study to be conducted there? ○ Yes ○ No

Date Submitted:

SSU00071153

View: Regulatory Inspection Information and IRB Considerations

Regulatory Inspection and IRB Considerations

1

We have the following regulatory inspections on file for the Investigator and/or your investigational/research location(s):

Type	Date	Audit Finding	Address

We do not have any Audit information on file for either the listed PI or for any of the Research Locations indicated for this submission

Please enter any ***regulatory inspections*** not listed above that have occurred in the last 5 years by clicking '**Add**':

Type	Date	Audit Finding	Address

There are no items to display

2

* Has the research study and/or your site been disapproved or withdrawn from another IRB? ○ Yes ● **No**

3

* If previously or currently approved by another IRB, are you requesting a transfer of IRB oversight? ●

Yes ○ No

Date Submitted:

SSU00071153 View: Transfer of Oversight Summary Status

Transfer of Oversight Summary Status

1

* Indicate the enrollment status for this research study for your investigational/research location(s):

- ○ Enrollment is pending and has not started
- ○ Enrollment is open and subjects are currently enrolled
- ○ Enrollment is open but no subjects have been enrolled
- ○ Enrollment is open and subjects were previously enrolled, but none are enrolled at this time
- ○ Enrollment is on hold and no subjects were enrolled prior to the hold
- ○ Enrollment is on hold but there are active subjects enrolled prior to the hold
- ○ Enrollment is on hold and subjects were previously enrolled, but none are enrolled at this time
- ○ Enrollment is closed, and there are`still active subjects
- ● **Enrollment is closed, and subjects are in follow-up only**
- ○ Enrollment is closed and there are no active subjects or follow-up being performed
- ○ Enrollment is closed and there are no active subjects or follow-up being performed, but requesting continued IRB oversight

2

For this research study at your investigational/research location(s), please answer the following questions:

* Number of Subjects who signed the Informed Consent Form:	10
* Number of Active Subjects:	0
* Number of Subjects who have completed all research study requirements:	5
* Number of Serious Adverse Events (SAEs):	1
* Number of Unanticipated Problems (UAPs):	1

Date Submitted:

SSU00071153 View: Conflict of Interest (Advarra)

Conflict of Interest

The following questions apply to any investigator, including PI, sub-I, research staff, and any other person who is responsible for the design, conduct, or reporting of the research.

The questions also apply to the immediate families of investigators (meaning their spouses and any dependent children)

"Relevant company" refers to an entity that sponsors provide support for, or owns or produces the technology being investigated.

1

* Have any of the above individuals received compensation from a relevant company (e.g., in exchange for consulting, speaking, or serving on an advisory board) that when aggregated for the immediate family for the prior 12 months is $5,000 or greater? *(Please note that salary paid to an investigator or research staff is NOT considered a reportable payment, UNLESS that salary is contingent upon the result of this study.)*

● **Yes** ○ No

* Please select the amount below:

- ● **$5K or greater, but less than $25K**
- ○ $25K or greater, but less than $50K
- ○ $50K or greater, but less than $75K
- ○ $75K or greater, but less than $100K
- ○ $100K or greater

* Describe the specific interest in detail, including the name and role of the conflicted individual, and the arrangement giving rise to the potential conflict (e.g., consulting, speaking, or serving on an advisory board for the sponsor)
ccccc

2

Do any of the above individuals have an ownership interest (e.g., stock) in a **publicly-held** relevant company that when aggregated for the immediate family for the prior 12 months is $5,000 or greater?

○ Yes ● **No**

3

* Do any of the above individuals have any ownership interest (e.g., stock, stock options) in a relevant company that is privately-held?

○ Yes ● **No**

* Do any of the above individuals have a proprietary interest being investigated in the research study (e.g., patent or licensing agreement)

○ Yes ● **No**

*

	Do any of the above individuals have a financial agreement with any company in which they receive, or will receive, compensation that is linked to the outcome of the research study?	○ Yes ● **No**
	* Do any of the above individuals serve as in an executive position or on the board of directors for a relevant company?	○ Yes ● **No**
	* Do any of the above individuals have any other financial or non-financial interests not listed above that could appear to potentially influence the conduct or outcome of this research study at the investigational/research location(s) or interfere with the ability to adequately protect research subjects?	○ Yes ● **No**
4	* Has an in-house Institutional Conflict of Interest Committee made any determinations and/or required any specific management plans related to this research for any of the above individuals? * Please provide a detailed description of the determinations/management plans: ccccc	● **Yes** ○ No
	Date Submitted:	

SSU00071153 View: Informed Consent Document

Informed Consent Document

The IRB will provide an ICF document(s) formatted with your information. Indicate below the information that you want included:

1

* Place a checkmark next to each address you want listed on the ICF document(s):

Address

- [ ] 2345 Liberty Road, Suite 250, Reisterstown, MD, 21127, USA
- [ ] 123 Main Street, Suite 200, Columbia, MD, 21045, USA
- [x] **123 Smith St, Columbia, MD, 21046, USA**

2

* Primary phone number to be listed on the ICF document(s): 444-444-4444

* 24-Hour phone number to be listed on the ICF document(s): 444-444-4444

3

* The following are questions related to monetary and non-monetary compensation, to include payment for participation and re-imbursement for expenses (travel, parking, etc.). Upon receipt of your application, **the IRB assumes that the amounts have been finalized and will proceed with review** unless further notification is received.

Provide the breakdown of compensation **or** reimbursement to subjects, including any gift cards, toys, or movie tickets. If you are **not** compensating and/or reimbursing subjects, then you can just indicate N/A:
subjects will be paid $35 per visit

4

* Timing of Monetary Payments:

- (●) **Subjects will be paid following each completed visit**
- ( ) Subjects will be paid monthly
- ( ) Subjects will be paid quarterly
- ( ) Subjects will be paid at the end of their participation in the research study
- ( ) Subjects will be paid following each completed visit or at the end of their participation in the research study, whichever they prefer
- ( ) There will be no payment/reimbursement to subjects
- ( ) Other

	If 'Other', please provide an explanation of timing of payment below:
5	List any visits for which subjects will not be paid:
6	* Will you need the Informed Consent Form translated into another language? ○ Yes ● **No** If yes, what language(s)? **Please note: The sponsor will need to approve the translation request before being released to your site**
7	* Are you requesting the IRB to grant a partial HIPAA Waiver? ● **Yes** ○ No
8	* Are you planning to use an electronic consent (eConsent) to enroll subjects? ● **Yes** ○ No

Date Submitted:

SSU00071153 View: eConsent Attestation

eConsent Attestation

1

Please confirm that your e-consent process meets regulatory requirements by answering 'Yes' to all that apply, below:

* If you are submitting paper-based consent forms, story boards, graphics, etc., the electronic consent will only include the information approved by the IRB. (If you planned to include inserted graphics and/or web links in the e-consent, answer 'NO' and please provide a summary and/or storyboard describing these media components.)	**Yes** ○ No
* The e-consent signature block is/will be in compliance with 21 CFR Part 11, subpart A (11.1)(a).	**Yes** ○ No
* The e-consent process will be IN-PERSON and is not planned for remote consenting. For remote consent, answer 'No' and provide a description of your remote consent process.	**Yes** ○ No
* The signed e-consents will be archived appropriately with restricted access with all versions easily retrieved.	**Yes** ○ No
* There will be an audit trail for each subject e-consent, identifying the subject, study staff, and date/time of the electronic signature(s) and PDF creation of the IRB approved informed consent.	**Yes** ○ No
* The subject will receive a copy of the signed electronic consent.	**Yes** ○ No
* The HIPAA signature block complies with The Electronic Signatures in Global and National Commerce Act (E-Sign Act)(Public Law 106-229).	● **Yes** ○ No ○ N/A

Per FDA guidance, it is recommended to add consent language informing subjects of the risks of storing or viewing the e-consent on a personal electronic device (PED), especially if that PED is shared with other users, is lost, hacked, or subject to a search warrant or subpoena. As such, the IRB will add this language as part of the informed consent form.

SSU00071153 View: Request for HIPAA Waiver

Request for Partial HIPAA Waiver

1	* Please describe your screening/recruitment method: cc
2	* Please describe how the use of PHI for identifying subject eligibility and contacting potential subjects is of minimal risk to the individual's privacy. **(Generally, a statement that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosures of protected health information would be permitted AND a description of the plan to protect the identifiers from improper use and disclosure)** cc
3	* When will screening data be either de-identified or destroyed? (generally a statement that ineligible patient's PHI will not be shared with the sponsor, and it will be destroyed or placed in a secure file until it can be destroyed) cc
4	* Please describe why recruitment cannot be carried out without the Partial Waiver of Authorization to use a potential subject's PHI: cc
	Date Submitted:

SSU00071153

View: Message to End User

Message to User

Changes Incorporated as of October 30, 2015:

To facilitate your application process, the next pages already display the current information we have on file for the investigator if you have submitted since October 30, 2015.

Update or edit as necessary. Any changes you make will be saved and available for future submissions.

Changes Incorporated as of December 9, 2016:

New questions were added to question #3 on the next page on December 9, 2016. These will have to be completed and saved on file even if you have submitted this since October 30, 2015.

SSU00071153 View: Investigator Experience and Qualifications

Investigator Experience and Qualifications

1

* How many years has the investigator been involved in the conduct of research? 1 or more years

2

What is the investigator's National Provider Identifier (NPI) Number (if applicable):

3

* What additional training, certifications, and/or degrees in the field of human research protections have been completed by the Investigator?

- [x] **OHRP Human Subject Assurance Training**
- [x] **NIH Online Course: Human Participant Protections Education for Research Teams (training must have occurred prior to September 27, 2018)**
- [x] **Investigator Meeting(s)**
- [ ] Collaborative Institutional Training Initiative (CITI) Program
- [ ] APPI [Certified Physician Investigator (CPI™)]
- [ ] ACRP [CTI, CCRC, CCRA]
- [ ] SOCRA [CCRP]
- [ ] Graduate/Undergraduate researcher studies/degree(s)
- [ ] DIA [CCI]
- [ ] Tri Council Policy Statement Course on Research Ethics (CORE)
- [ ] Clinical Research Association of Canada (CRAC)
- [ ] Academy of Physicians in Clinical Research (APCR)
- [ ] Other

* You indicated 'Investigator Meeting(s)' or 'Other' above. Please provide a description of the human research protections training received:xxx

4

* What is the current number of research studies supervised by the Investigator? 4
* What is the approximate number of active research subjects currently supervised by the Investigator? 30
* How many Sub-Investigators with clinical trials experience are assisting the Investigator? 4
* How many research staff members with clinical trials experience are assisting the Investigator? 1

If there are any other resources available at your site to support the administration of any active clinical trials, please provide them here:

Questions 4-9 ask about the investigator's specialties and research experience. The IRB may share this information with Sponsors or organizations acting on their behalf to identify investigator candidates for future research studies. You may opt out of those disclosures by checking the box here. ☐

5

* Specialty of the investigator (if applicable): Allergy & Immunology

6

* Sub-specialty(s) - (if any)

Sub-Specialty

Pain Medicine

7

* What phases of research has the investigator conducted (if applicable)?

- ☐ Phase 0
- ☐ Phase 1
- ☑ **Phase 2**
- ☐ Phase 3
- ☐ Phase 4
- ☐ N/A

8

* In which therapeutic areas does the investigator have research experience?

Therapeutic Area

Dermatology

9

* In which following disease/general areas does the investigator have research experience?

Diseases/General Areas

- ☐ _None
- ☑ **Blood, Blood-forming Organs Diseases**
- ☐ Circulatory System Diseases
- ☐ Dental and Oral Health
- ☐ Digestive System Diseases

Ear/Mastoid Process Diseases

Diseases/General Areas

- [ ]
- [ ] Endocrine Diseases
- [ ] Endocrine, Nutritional, and Metabolic Diseases
- [ ] Eye/Ocular Adnexa Diseases
- [ ] Genitourinary System Diseases
- [ ] Infectious and Parasitic Diseases
- [ ] Mental/Behavioral Disorders
- [ ] Metabolic Diseases
- [ ] Musculoskeletal/Connective Tissue Diseases
- [ ] Neoplasms
- [ ] Nervous System Diseases
- [ ] Nutritional Diseases
- [ ] Pain Management
- [ ] Pelvis, Genital, and Breast Diseases
- [ ] Perinatal Diseases/Conditions
- [ ] Pregnancy-Related Diseases
- [ ] Respiratory System Diseases
- [ ] Skin/Subcutaneous Tissue Diseases
- [ ] Social and Behavioral Research
- [ ] Urinary System Diseases

10

* What age groups does the investigator have research experience (if applicable)?

- [x] **Adolescents**
- [ ] Adults
- [ ] Adults-Older
- [ ] Children
- [ ] Infants
- [ ] Neonates
- [ ] None

Date Submitted:

SSU00071153

View: Site and Local Context Information

Site and Local Context Information

1

* Indicate any state or local laws having an impact on research at your investigational/research location(s) by checking all that apply:

- [x] **None**
- [ ] Mandatory IRB Site Visits
- [ ] Age of Majority is 19 years (US states of AL, NE & Canadian provinces of BC, NB, NL, NS) or 21 years for Puerto Rico
- [ ] California Experimental Subject's Bill of Rights
- [ ] State Privacy laws related to the use of Protected Health Information (PHI)
- [ ] Other

If 'Other', please explain:

2

* Which, if any, of the following pending or on-going actions or restrictions related to the practice of medicine or research apply at your location(s) [including the PI and the research staff]

- ○ Legal
- ○ Regulatory
- ○ Professional
- ○ Other
- ● **None of the above**

If any, please explain:

3

* What recruitment methods may be used at your site?

- [ ] In conversation during routine office visits
- [ ] Rollover or extension or participation from another research study
- [ ] Mass distributed print publication (ex: newspaper, magazine, newsletter)

- [ ] Flyer, poster or bulletin board
- [x] **Radio**
- [ ] Television
- [ ] Direct Mailing
- [ ] Internet
- [x] **Database/Chart Review**
- [ ] Telephone Screening Script
- [ ] Other

If 'Other', please explain:

4

* Will you be paying any professionals for their assistance in the recruitment of potential subjects (for example: finder's fees, referral fees, etc.) ○ Yes ● **No**

If 'yes', please explain:

5

* Do any of your research location(s) have a local IRB that the PI is required to submit to? ● **Yes** ○ No

* You indicated that there is a local IRB. Please select one of the following:

No oversight waiver is required

6

* Does your site hold a Federal Wide Assurance (FWA?) ● **Yes** ○ No

If 'yes', please provide your number: FWA-11111

7

* How would you describe the attitudes about research held by potential research subjects in your community?

- ○ Positive
- ● **Neutral**
- ○ Negative

If negative, give a brief explanation:

8	* Has there been any recent media focus on research in your community? ◯ Yes ● **No** If yes, give a brief description:
	Date Submitted:

SSU00071153 View: Recruitment through Database/Chart Review

Recruitment through Database/Chart Review

Because it has been indicated that Database/Chart Review will be utilized as a recruitment method, respond to the following:

1 * What sources of data will be reviewed for recruitment of potential subjects? Check all that apply:

- [x] **Electronic Database**
- [x] **Medical records/charts/paper records**
- [ ] Other

If Other, give a brief description:

1a * Who has ownership of these sources of data, databases and/or charts? vvvv

2 * Will you compare the Inclusion/Exclusion criteria found in the protocol document with the potential subject's information to determine eligibility? (●) **Yes** ( ) No

3 * What method(s) will the research staff use to preserve the privacy and confidentiality of this information?

- [x] **Locked cabinet/room accessible only to authorized staff**
- [x] **Password protected database accessible only to authorized staff**
- [x] **Coded subject identifiers**
- [ ] Other

If Other, give a brief description:

Date Submitted:

SSU00071153

View: Informed Consent Process, Data Privacy and Confidentiality

Informed Consent Process, Data Privacy and Confidentiality

1

* The informed consent process is an ongoing, continuous process. It is the IRB's expectation that ongoing consent of the subject is ensured by the Investigator during the course of the research study.

To comply with the conditions of IRB Approval, the following procedures must be followed during the informed consent process at your location(s):

a. The Investigator will not involve any individual in the research study unless the Investigator has obtained the legally effective informed consent of the potential research subject (or legally authorized representative [LAR]).

b. The potential research subject (or LAR) is provided sufficient opportunity to consider whether to participate in the research study.

c. The consent process minimizes the possibility of coercion or undue influence.

d. The consent discussion is in a language understandable to the potential research subject (or LAR).

e. The consent discussion is free from the use of any exculpatory language.

f. Procedures required only for the research study will not be performed prior to obtaining consent

g. The most recent IRB Approved version of the ICF is used for enrollment.

h. The potential research subject (or LAR) is given adequate time and a place to read and review the ICF.

i. The potential research subject (or LAR) is given the opportunity to take the ICF home for review prior to signing the document, as appropriate.

j. The consent discussion provides ample opportunity for the Investigator (or sub-investigator with equivalent qualifications to serve as Investigator) to be available to answer questions the potential research subject (or LAR) may have.

k. Each person on the IRB Approved ICF signs and dates the form on the same visit, as appropriate. The potential research subject (or LAR) receives a signed and dated copy of the ICF

l. The consent discussion includes an assessment of the subject's understanding of the study following the consent process and before being enrolled in the study

Do you (the Investigator) and your research staff (if applicable) agree to comply with the conditions regarding the informed consent process as outlined above?

- (●) **I agree with the process**
- ( ) I disagree.**

**If you do not agree, provide an explanation:

2

* Do you conduct competing research studies? *(This does not include research with healthy subjects)*

Yes **No**

3

* Please specify the location at your site where the informed consent process will be conducted with a potential subject (or their LAR) [check all that apply]:

- [x] **In a private room/area**
- [ ] In a group setting
- [ ] Other

If Other, please explain:

4

* Please specify the steps taken by the Investigator and authorized research staff to minimize the possibility of coercion or undue influence during the informed consent process (check all that apply):

- [x] **The informed consent discussion is presented to the subject (or their LAR) by someone who is sufficiently knowledgeable about the research to properly interpret and correctly answer questions.**
- [x] **The subject (or their LAR) is not pressured to participate in the research and is not penalized or excessively questioned for deciding not to participate in the research.**
- [x] **The consent presentation is discussed in non-technical language understandable to the subject (or their LAR) and the subject's (or LAR's) understanding is confirmed through an unrushed two-way conversation.**
- [ ] Other

If Other, please explain:

5

* Please specify the steps taken by the Investigator and authorized research staff to ensure that the subject (or their LAR) is provided sufficient opportunity to consider participation in the research (check all that apply):

- [x] **The subject (or their LAR) is given adequate time and place to read and review the Informed Consent Form and ask questions.**
- [x] **The subject (or their LAR) is given the opportunity to take the Informed Consent Form home for review prior to signing the document.**
- [x] **The subject (or their LAR) is provided a sufficient waiting period between being informed of the research and signing the consent form.**
- [ ] Other

If Other, please explain:

6

* How will the subject's data identifiers be recorded?

	● **Identifiers will be anonymized, coded, or de-identified as outlined in the protocol or our standard operating procedures/policies** ○ Other If Other, specify:
7	* Choose all the mechanisms in place to ensure that the research records/data will be kept to protect the privacy and confidentiality of subject information: ☑ **Paper-based records will be kept in a secure location only accessible to authorized staff** ☑ **Computer-based files will be available only to authorized staff using access privileges and passwords** ☐ Other If Other, specify:
	Date Submitted:

SSU00071153

View: Document Upload Page

Document Upload Page

	Please attach all documentation necessary for IRB review in the **correct areas outlined below**:
1	* CV of Investigator: Blank upload CIRBI document.docx(0.01)
2	Medical License Number:
3	IRB Waiver of Oversight (if applicable): No Waiver of Oversight Document Uploaded
4	Site Specific Recruitment/Subject Facing Material: Type of Material Name Type Category Document Status There are no items to display
5	Please upload any other attachments here: There are no items to display

Date Submitted:

SSU00071153

View: End of Application

End of Application

* Please select one of the options below and then click **'Continue'**. If you select **'Submit Application'**, the IRB review process will begin. Save Application, but DO NOT submit

****Note if you select "Submit Application", then you are attesting to the following:**

The Investigator for this protocol is responsible for and attests to the following:
a) Not starting the research study prior to receiving IRB Approval
b) Personally conducting or supervising the described investigation(s)
c) Ensuring that all associates, colleagues, and employees assisting in the conduct of the research study are informed about their obligations in the conduct of the research
d) Utilizing only the IRB Approved Informed Consent Form/eConsent to enroll subjects
e) Obtaining appropriate informed consent from potential research subjects prior to performing any research procedures ("If changes are made due to immediate danger to a subject, immediately report these change to the IRB")
f) Making no changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects
g) Complying with all federal, state, provincial, and local regulations regarding the conduct of research
h) Ensuring your investigative/research location(s) are conducting this research in compliance with the policies and procedures outlined in the IRB Handbook located in the Reference Materials Section of CIRBI.
i) Including in the contract (or other agreement) with the Sponsor that results/new findings from a research study directly affecting subject safety or their medical care will be communicated to subjects and how that communication will occur.
j) Including in the contract (or other agreement) with the Sponsor that any findings from a research study discovered by the Sponsor that could affect the safety of participants, affect the willingness of participants to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study will be communicated and subsequently reported to the IRB by the Investigator.

Date Submitted: