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SPONSOR: _____	PROTOCOL #: _____
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A. PRINCIPAL INVESTIGATOR and RESEARCH SITE INFORMATION

1.	Name of previously approved Principal Investigator:	
2.	Name of new Principal Investigator:	
3.	Name of research site:	
4.	Site contact name:	
5.	Site contact phone number:	
6.	PI's direct phone number for Board inquiries:	
7.	Site mailing address:	
8.	Site contact E-mail address:	
9.	Site Fax number:	
10.	Site 24 hour phone number for participants:	
11.	The following documents must be included with this submission:	<input type="checkbox"/> The Principal Investigator's current professional license. <input type="checkbox"/> The Principal Investigator's current CV. <input type="checkbox"/> FDA Form 1572 (DRUG studies only) <input type="checkbox"/> Completed and signed FORM 515 <input type="checkbox"/> Documentation of required training
12.	For DRUG studies taking place in Massachusetts, include:	<input type="checkbox"/> Researcher License <input type="checkbox"/> DEA License
13	Is there any pending disciplinary action against the Investigator from ANY state licensing Board?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)

B. FDA INSPECTIONS

1.	Has the Principal Investigator been disciplined or restricted by the FDA?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
2.	Has the Principal Investigator been subject to an FDA inspection within the past 2 years?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
3	Has the Principal Investigator been debarred by the FDA?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)

C. PRINCIPAL INVESTIGATOR STATEMENT of AGREEMENT

As the Principal Investigator for the above referenced clinical investigation, I accept full responsibility for:

1. Reviewing the protocol (and Investigator's Brochure if applicable) in its entirety, and conducting the clinical investigation according to the RCRC IRB approved protocol. Ensuring that all research staff comply with the requirements of the protocol, and for reporting all incidences of non-compliance to RCRC IRB.
2. Ensuring adequate and reliable financial and/or other resources are available to conduct the research and halt research procedures should any of these resources become unavailable.
3. Ensuring that all research staff assisting in the conduct of the clinical investigation are informed about their obligations in meeting the requirements of 21 Code of Federal Regulations Parts 50 and 56 and have the training and education to follow the requirements. Ensuring consideration of all applicable federal regulations, local and/or state laws pertinent to the research site, and consideration of community attitudes in terms of religious, ethnic, or economic status of the community from which research subjects will be drawn, relative to the clinical investigation at my site.
4. Providing a copy of the RCRC IRB approved Informed Consent Document to research participants at the time of consent, and for not enrolling any individual into this research study until voluntary consent has been appropriately obtained and documented. Ensuring that each potential subject is provided with the information needed to understand the nature and potential risks of the research, and for taking necessary steps for the individual to gain that comprehension.
5. Ensuring that no individual is recruited into this clinical investigation: (a) until the study has been approved in writing by RCRC IRB; (b) during any period wherein RCRC IRB approval of this research study has lapsed; (c) during any period wherein RCRC IRB approval of the research or participant enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; (d) following termination of RCRC IRB approval of the research; or (e) following expiration of the approval period as established by RCRC IRB.
6. Promptly assessing and reporting all unanticipated problems that are unexpected, serious, and definitely or probably related and any death that occurs during the time of enrollment when a participant has received investigational agent and up to thirty (30) days following last dose of/exposure to the investigational agent, within 10 days of being informed of the event. Ensuring that participants who have suffered an unanticipated problem associated with research participation receive adequate care to correct or alleviate the consequences of the event to the extent possible, and arranging for the treatment of a research related injury with the Sponsor. Promptly reporting information received from an independent monitoring board if the information could impact participant safety. The Sponsor has an ethical obligation to provide care to a research participant for the treatment of injuries resulting from participation in that Sponsor's research. This includes clinical care or psychological support.
7. Promptly reporting all proposed changes in previously approved research to RCRC IRB, and making no changes in approved research except when necessary to eliminate an apparent immediate hazard to a research participants, and for promptly reporting to the IRB any non adherence to the currently approved research protocol. Making no changes to the information provided to research potential or active participants, such as study material in electronic or print format. Promptly reporting any changes in the Principal Investigator's address or other contact information and seeking approval for an additional research facility prior to initiation. Promptly reporting any changes to the Financial Disclosure/Conflict of Interest information that was initially disclosed; or occurrences of undue influence.
8. Ensuring that research participants are kept fully informed of any new information that may affect their willingness to continue participation in the clinical investigation, and for responding appropriately and adequately to all inquiries, complaints, or concerns from research participants and reporting any concerns that affect the safety, rights, or welfare of the participant. Promptly reporting any changes to the participant population, or in the vulnerability of participants.
9. Keeping adequate, current, and accurate records of research data, outcomes, and unanticipated problems to permit an ongoing assessment of the risks/benefit ratio. Storing this information in a secure and confidential manner such as a password protected database, or locked filing cabinet to which direct access is controlled and/or monitored. Maintaining each participant's information in such a way as to protect the privacy of the individual and the confidentiality of the data.
10. Seeking timely review and approval for continuing the clinical investigation in accordanc with 21 CFR 56.109 (f), prior to the expiration date to avoid, suspension and/or termination of the research. Notifying RCRC IRB upon completion of the clinical investigation and promptly submitting a Final Report prior to the expiration date of the approval period. Responding promptly to all requests for information or materials from RCRC IRB Board Members or Staff.

11. In Drug studies: Taking responsibility for the control of drugs under investigation, and for ensuring that an investigation is conducted according to the signed agreement, the investigational plan, and applicable FDA regulations. Administering the drug only to participants under my supervision or the supervision of my designee(s). Supplying the investigational product (IP) only to those individuals who are authorized to receive it. Maintaining adequate records of the product's delivery to the trial site, the use by each participant, and the disposition of the drug including dates, quantities and batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the IP. Storing the IP as specified by the Sponsor and in accordance with applicable regulatory requirements. Preparing and maintaining adequate and accurate records of all observations and other data pertinent to the investigation on each individual administered the investigational drug, or who is a control in the clinical investigation. Maintaining records that document adequately that the participants were provided the doses specified in the protocol and reconcile all IP received from the sponsor.
12. In Device studies: Taking responsibility for ensuring that an investigation is conducted according to the Investigational Plan, and applicable FDA regulations, and for the control of devices under investigation. Maintaining records of receipt, use, or disposition of a device that relate to the type and quantity of the device, the dates of its receipt, and the batch number, or related code. The names of all persons who received, used, or disposed of each device; why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of. Preparing and maintaining adequate and accurate records of each participant's exposure to the device including records concerning adverse device affects, whether anticipated or unanticipated, information and data on the condition of each participant upon entering, and during the course of the investigation, including information about relevant previous medical history and the results of all diagnostic tests. A record of the exposure of each participant to the investigational device, including the date and time of each use, and any other therapy; the protocol, with documents showing the dates of and reasons for each deviation from protocol; any records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

My signature below indicates that I agree to assume the responsibilities for the safe and ethical conduct of the research and to abide by the decisions and requirements of RCRC IRB. I understand that it is my obligation to review the reporting responsibilities, as provided on their website and to me in printed form. I understand I may contact RCRC IRB at any time with questions or concerns about these requirements. I understand that failure to comply with the above requirements may result in regulatory action by RCRC IRB. By signing this agreement, I grant RCRC IRB the authority to approve and oversee the above referenced clinical investigation.

The information provided on this document is true and accurate to the best of my knowledge.

Signature of Principal Investigator: _____ Date _____

D. LIST of ATTACHMENTS

REQUIRED DOCUMENTS:

- The Principal Investigator's current professional license and current CV, signed and dated within two years
- For investigational DRUG studies only: FDA Form 1572.
- For SINGLE site DEVICE studies only: Investigator's commitment to the sponsor.
- Attached explanation for any question answered "Yes" that requires an attachment.**
- Completed and signed Conflict of Interest Form (FORM 515)
- Documentation of required training

REQUIRED DOCUMENTS FOR DRUG STUDIES IN MASSACHUSETTES:

- DEA License (controlled substance)
- Researcher License