



**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
**Page 1 of 9**

*Please answer each question completely. For those questions requiring additional explanation, please attach materials and return with this form. Any question left blank or incomplete will delay your review. This study cannot be reviewed by the IRB until this form and all supporting documentation are received.*

<b>SECTION 1: GENERAL STUDY INFORMATION</b>	
a. Sponsor: _____	b. Protocol #: _____
c. Protocol Title: _____	
<b>SECTION 2: PRINCIPAL INVESTIGATOR CONTACT INFORMATION</b>	
a. Principal Investigator (PI) Name: _____	
b. Site Name: _____	
c. Address: _____	
City: _____	State: _____ Zip Code: _____
d. Mailing Address – <i>should be the same as the address listed in Box #1 of FDA Form 1572 or equivalent</i> <input type="checkbox"/> Same as above	
Address: _____	
City: _____	State: _____ Zip Code: _____
e. PI Phone Number: _____ PI FAX Number: _____	
24-hour Phone Number to be listed in Informed Consent Document: _____	
PI e-mail: _____	
f. Study Coordinator Name: _____	
Business Phone Number: _____	FAX Number: _____
Study Coordinator e-mail: _____	
<b>SECTION 3: TEST ARTICLE INFORMATION</b>	
a. Test Article Name: _____	
b. Please check the appropriate box(es):	
<input type="checkbox"/> The device is FDA approved for the indication in this study.	
<input type="checkbox"/> 510k clearance or PMA determination from the FDA ( <i>attach a copy of a FDA generated letter</i> )	
c. If the device is not FDA approved, please check the appropriate box:	
<input type="checkbox"/> Proof of an FDA initiated IDE number: _____	
<i>(Please provide your IDE# or attach a FDA generated letter confirming that you have applied for an IDE)</i>	
<input type="checkbox"/> Letter from the Sponsor ( <i>on letterhead</i> ) stating why this device is classified as Non-Significant Risk in accordance with 21 CFR 812.3 (m)	
b. If the device is exempt from IDE regulations, please check the appropriate box:	
<input type="checkbox"/> It is a low risk device that meets FDA exemption from premarket review	
<input type="checkbox"/> It is an <i>In Vitro Diagnostic Device (IVD)</i> Study that meets the following requirements: The testing is non-invasive; does not require invasive sampling presenting significant risk; does not introduce energy into a subject; and is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic device or procedure.	

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
*Page 2 of 9*

<b>SECTION 3a: ADDITIONAL CONSIDERATIONS</b>	
a.	Does the device involve the use of ionizing radiation or isotopes? <input type="checkbox"/> No <input type="checkbox"/> Yes
b.	Will the sponsor will be charging the Principal Investigator and / subjects for the device? <input type="checkbox"/> No <input type="checkbox"/> Yes - <i>If yes, attach a rationale and a description of the amount to be charged to PIs / subjects.</i>
<b>SECTION 4: IRB REVIEW INFORMATION</b>	
a.	Has this study ever been submitted to another IRB for review? <input type="checkbox"/> Yes - <i>list the name of the IRB(s) and the outcome of the review(s) on a separate page.</i> <input type="checkbox"/> No
<b>SECTION 5: SPONSOR INFORMATION</b>	
<b>Contact Person:</b> _____ <b>Company:</b> _____ <b>Address:</b> _____ <b>City:</b> _____ <b>State:</b> _____ <b>Zip Code:</b> _____ Phone Number: _____ FAX Number: _____ email: _____	
<b>SECTION 6: CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION</b> <span style="float: right;"><input type="checkbox"/> None</span>	
Contact Person: _____ Company: _____ Address: _____ City: _____ State: _____ Zip Code: _____ Phone Number: _____ FAX Number: _____ email: _____	
<b>SECTION 7: SITE MANAGEMENT ORGANIZATION (SMO) INFORMATION</b> <span style="float: right;"><input type="checkbox"/> None</span>	
Contact Person: _____ Company: _____ Address: _____ City: _____ State: _____ Zip Code: _____ Phone Number: _____ FAX Number: _____ email: _____	
<b>SECTION 8: MAIL DELIVERY INFORMATION</b>	
f.	How would your site prefer to receive study documents? ( <i>check one</i> ) <input type="checkbox"/> As per Sponsor / CRO instructions <input type="checkbox"/> Regular Mail <input type="checkbox"/> Overnight Courier Service ( <i>account number required</i> ) <input type="checkbox"/> FedEx <input type="checkbox"/> DHL <input type="checkbox"/> UPS <input type="checkbox"/> Other: _____ Account Number: _____

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
**Page 3 of 9**

**SECTION 9: PRINCIPAL INVESTIGATOR**

*If supporting documentation has been previously submitted to Aspire, there is no need to re-submit. Simply check "Yes" and "On File". However, changes or new information must be submitted to Aspire in a timely manner.*

- a. Please provide a copy of the PI's signed and dated CV (*current within the past 2 years*)  On File
- b. PI Specialty(ies):  
 Board Certified?  Yes-please describe:  No
- c. Medical License (*please attach copy*) Expiration Date: \_\_\_\_\_  N/A
- d. DEA Registration (*please attach copy, if applicable to this study*) Expiration Date: \_\_\_\_\_  N/A
- e. FOR PI's CONDUCTING RESEARCH WITH INVESTIGATIONAL DRUGS IN MASSACHUSETTS  N/A  
 Have you attached a copy of your current MA Department of Public Health Registration?  Yes  On File  No
- f. Has the PI's license ever been suspended, revoked, placed on probation or restricted at any facility?  
 No  Yes – *please provide explanation*  On File
- g. Have the PI's hospital privileges ever been suspended, revoked, placed on probation or restricted at any facility?  
 No  Yes – *please provide explanation*  On File
- h. Has the PI ever been charged with a misdemeanor or felony that relates to the practice of medicine?  
 No  Yes – *please provide explanation*  On File
- i. Has the PI ever had an IRB impose any sanctions or restrictions on him / her?  
 No  Yes – *please provide explanation*  On File
- j. Has the PI ever had an IRB terminate or suspend its approval of a study for any reason?  
 No  Yes – *please provide explanation*  On File
- k. Has the PI ever undergone a FDA/OHRP audit, received a FDA 483 (within the past 5 years), Warning Letter or NIDPOE (*Notice of Initiation of Disqualification Proceedings and Opportunity to Explain*)?  
 No  Yes – *please provide copies of all letters and correspondence*  On File

**SECTION 10: PRINCIPAL INVESTIGATOR (continued)**

- l. How long has the PI been conducting research?  First study  < 1 year  1-5 years  > 5 years
- m. On how many studies is the PI current listed as the Principal Investigator? \_\_\_\_\_  
 On how many studies is the PI current listed as a Sub-Investigator? \_\_\_\_\_
- n. Has the PI attended any training specific to this study  
 (*i.e., Investigator Meeting, Site Initiation Visit or industry sponsored education*)?  
 Yes  No – *If no – indicate the date when the PI will complete this training:* \_\_\_\_\_
- o. Principal Investigators are required to complete research related training and/or education in the area of Good Clinical Practices and Protection of Human Subjects. Has the PI met this requirement within the past two years?  
 Yes  On File  No

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
*Page 4 of 9*

**SECTION 11: SUB-INVESTIGATORS**

The following questions relate to Sub-investigators listed in Box #6 of the FDA Form 1572 or equivalent. If there are no Sub-investigators assisting the Principal Investigator with this study, please check N/A here  and proceed go to SECTION 8.  
*If supporting documentation has been previously submitted to Aspire, there is no need to re-submit. Simply check "Yes" and "On File". However, changes or new information must be submitted to Aspire in a timely manner.*

- a. Provide copies of all Sub-investigator qualifications (i.e., CVs and current licenses)  On File
- b. Has any Sub-investigator's medical license ever been suspended, revoked, placed on probation or restricted?  
 No  Yes – *please provide explanation*  On File
- c. Has any Sub-investigator's hospital privileges ever been suspended, revoked, placed on probation or restricted at any facility?  
 No  Yes – *please provide explanation*  On File
- d. Has any Sub-investigator ever had an IRB impose any sanctions or restrictions on him/her?  
 No  Yes – *please provide explanation*  On File
- e. Has any Sub-investigator ever had an IRB terminate or suspend its approval of a study for any reason?  
 No  Yes – *please provide explanation*  On File
- f. Has any Sub-investigator ever been charged with a misdemeanor or felony that relates to the practice of medicine?  
 No  Yes – *please provide explanation*  On File
- g. Has any Sub-investigator ever undergone a FDA/OHRP audit, received a FDA 483 (within the past 5 years), Warning Letter or NIDPOE  
*(Notice of Initiation of Disqualification Proceedings and Opportunity to Explain)?*  
 No  Yes – *please provide copies of all letters and correspondence*  On File

**SECTION 12: CONFLICT OF INTEREST**

- a. Does the PI, any Sub-investigator, member of the study staff and/or their immediate families have ownership in the study?  
 No  Yes – *please explain how your site will manage the potential conflict of interest*
- b. Will the PI, any Sub-investigator, member of the study staff and/or their immediate families receive monetary consideration, excluding payment for the conduct of the study, for \$50,000 or more?  
 No  Yes – *please explain how your site will manage the potential conflict of interest*

**SECTION 13: SUBJECT ENROLLMENT INFORMATION**

- a. What is the subject enrollment goal for the study/protocol? \_\_\_\_\_
- b. Please provide the anticipated dates for the following events:  
 First subject enrolled: \_\_\_\_\_ Last subject enrolled: \_\_\_\_\_ Last subject completed: \_\_\_\_\_

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
*Page 5 of 9*

**SECTION 14: SUBJECT RECRUITMENT**

*All subject recruitment materials must be approved by Aspire prior to use.*

- a. Please indicate how you plan to recruit subjects for this study (*check all that apply*)
- Patient Database (PI's patients)     Referrals (*Aspire does not allow referral fees*)
- Database (other than PI's patient database) – Describe (*i.e., disease registry, CRO database, etc.*):
- Print Ads     Radio Ads     TV Ads     Newsletters     Flyers     Internet
- Doctor to Subject Letter     Doctor to Doctor Letter(s) (*does not require IRB approval*)     Other:
- b. Will audio or videotapes, photographs, DVDs, or other electronic records be made during any subject visits?
- Yes - *explain how you will maintain subject confidentiality*     No

**SECTION 15: COMPENSATION FOR PARTICIPATION**

- a. Will study subjects be compensated for their participation in the study?
- Yes - *complete all of SECTION 15*     No - *go to SECTION 16*
- b. Subjects will be compensated for their participation in the research study as follows:
- Total number of study visits: \_\_\_\_\_
- Compensation for Screening Visit(s): \_\_\_\_\_  N/A
- Compensation per completed study visit: \_\_\_\_\_
- Additional compensation: \_\_\_\_\_  N/A
- Compensation for telephone contact(s): \_\_\_\_\_  N/A
- Total compensation: \_\_\_\_\_
- Please attach a separate page if patient compensation is more complex than the breakout listed above.***
- c. How will subjects receive their compensation?     Cash     Check     Other – *attach an explanation*
- d. When will subjects receive their compensation?
- At each visit     At study completion     Other - *attach an explanation*
- e. Will subjects receive any alternate form of compensation (*i.e., gift certificates, free or reduced transportation, meals, parking, hotel accommodations, medications, etc.*)?
- Yes - *provide an explanation and an approximate value*     No

**SECTION 16: COMMUNITY INFORMATION**

- a. Are there any state or local laws governing the conduct of research in your community or state?
- Yes - *attach appropriate information / materials.*     No
- b. Are you aware of any community attributes (*i.e., religious, ethical, ethnic, economic, political*) that may affect the conduct of research at your study site(s)?
- Yes - *attach an explanation.*     No

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
**Page 6 of 9**

**SECTION 17: STUDY DEMOGRAPHICS**

Check all boxes that are applicable to the subjects you will recruit for this study:

- a. Gender:     Male     Female
- b. Ethnic Background(s):  
 Caucasian     African-American     Hispanic     Native American     Asian     Other - *explain*
- c. Economic Status:     Upper Income     Middle Income     Lower Income     All Applicable
- d. Will any gender or group be excluded from the study?  
 Yes - *attach a rationale for the exclusion.*     No

**SECTION 18: VULNERABLE SUBJECTS**

*Vulnerable subject populations must be provided with additional safeguards during the recruitment and consenting processes. Please indicate whether any of the following vulnerable subject populations may be enrolled in this study. A description of the specific measures your site will use to safeguard these vulnerable subjects during the recruitment / consenting process should be included with your submission materials.*

- Minors (anyone under the age of majority in your state)  
*Note: 18 yr. olds are considered minors in Alabama and Nebraska.*
- |   |   |
|---|---|
| <input type="checkbox"/> Economically and/or Educationally disadvantaged    | <input type="checkbox"/> Limited or non-readers / illiterate  |
| <input type="checkbox"/> Nursing Home Residents / Institutionalized Persons | <input type="checkbox"/> Decisionally impaired <input type="checkbox"/> Hearing / visually impaired |
| <input type="checkbox"/> Employees / Immediate family                       | <input type="checkbox"/> Students   |
| <input type="checkbox"/> Pregnant women / fetuses                           | <input type="checkbox"/> Life threatening condition / Terminally ill                                |
- Other (specify): \_\_\_\_\_
- Non-English speaking - *complete questions a & b below*
- a. Do you require a translated consent form?  
 Yes – *contact Aspire IRB upon receipt of your initial approval documents to request specified language*  
 No
- b. Will there be someone onsite to communicate with subjects in their primary language?  
 Yes  
 No - *please explain how you plan to communicate with the subject during the consent process and the subsequent study visits.*
- Do not anticipate the recruitment/enrollment of any subjects from vulnerable populations. *Note: In the event that a subject from a vulnerable population presents him/herself as a potential study subject, the Board should be notified and presented with a description of the specific measures that will be used to safeguard the vulnerable subject during the consenting and enrollment processes.*

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
*Page 7 of 9*

**SECTION 19: CONFIDENTIALITY AND HIPAA INFORMATION**

*If any of your study sites are considered "covered entities" as defined by the HIPAA Regulations please note that it is the Principal Investigator's responsibility to ensure that all research activities conducted at the sites are HIPAA compliant.*

- a. Please indicate the precautions the site will use to maintain subject confidentiality - *check all that apply*
- Paper based records will be kept in a secured location and only accessible to personnel involved with the study.
  - Computer based files will be password protected and only be made available to personnel involved with the study.
  - Study personnel will be required to sign statements agreeing to protect the security and confidentiality of study information prior to being granted access to any study related information.
  - When feasible, identifiers will be removed from study related information.
  - Other – *provide an explanation.*
- b. Will personnel not directly related to the research have access to study records or data (billing office, medical records, hospital personnel, etc.)?
- No     Yes - *provide an explanation*
- c. Will you be submitting HIPAA language for review?
- No     Yes - *submit as a separate HIPAA authorization document or as a clearly identified HIPAA section in the Informed Consent.*
- d. If any of your study sites are covered entities, will you require a HIPAA waiver or partial waiver of authorization in order to screen for the study?
- No     Yes - *provide the IRB with your rationale for this need.*

**SECTION 20: BILLING INFORMATION**

- a.  Bill Sponsor / CRO - *go to SECTION 17*    **OR**     Bill Principal Investigator – *complete remainder of SECTION 16*

b. Contact Person: \_\_\_\_\_ Title: \_\_\_\_\_  
Phone: \_\_\_\_\_ FAX: \_\_\_\_\_ email: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

***Payments should be sent with a copy of the invoice(s) to:  
Aspire IRB, 9320 Fuerte Drive, Suite 105, La Mesa, CA 91941.***

***Please note: Any changes to billing information must be sent to Aspire IRB at [Alycia@aspire-irb.com](mailto:Alycia@aspire-irb.com).***



**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION**  
**[SINGLE SITE]**  
*Page 8 of 9*

**SECTION 21: INVESTIGATOR AGREEMENT WITH ASPIRE IRB**

As the Principal Investigator, I agree to uphold ethical standards and practices in research, conduct research in accordance with applicable State and Federal regulations and requirements of Aspire as follows:

- Conduct this study according to the approved protocol and in accordance with 21CFR Parts 50, 56 and 312 and any additional conditions imposed by the IRB or FDA.
- Supervise all testing of the device involving human subjects.
- Agree to protect the rights, safety and welfare of the subjects to the best of my ability.
- Assure that there is written IRB approval prior to initiating or making any changes to the research except when it is necessary to eliminate apparent and immediate hazards to human subjects.
- Obtain IRB approval of all recruitment materials prior to their use.
- Assure that my designee or I use only the IRB approved informed consent form(s) and allow subjects sufficient time to consider their participation in this study.
- Submit Research Status Report forms in a timely manner.
- Report significant Protocol Deviations / Violations within 10 days.
- Report Unanticipated Device Effects and unanticipated problems involving risk to subjects or others that occur at my site within 5 calendar days from the date of discovery.
- Inform the IRB of any negative information concerning the device and/or protocol.
- Inform the IRB of the identification of significant risks that would require modifications to the protocol for the protection of study subjects.
- Respond to all requests from the IRB in a timely fashion.
- Disclose to the IRB any unfavorable decisions as well as positive decisions.
- Notify the IRB in writing when the study has closed.

I certify that the information provided in this application is true and correct. As Principal Investigator, I am requesting that Aspire review the information submitted. I understand that Aspire accepts responsibility for providing IRB oversight of this research. I understand that Aspire has the right to conduct a site visit at anytime with proper notification.

My signature below indicates that I will comply with my responsibilities as Principal Investigator in accordance with applicable regulations for the protection of human subjects.

Principal Investigator Name (Printed)

Signature of Principal Investigator

Date

**INVESTIGATOR INITIAL DEVICE STUDY APPLICATION  
[SINGLE SITE]**

*Page 9 of 9*

**INITIAL STUDY CHECKLIST**

The following information must be included with you completed application by the submission deadline in order to be guaranteed placement on the agenda. Do not forget to include this page with your application.

Please ensure the following items are included with this application:

- A written protocol that includes a statement of the name, purpose and intended use of the device along with objectives and duration of the investigation.
  - Risk analysis of all subjects.
  - Description of the device that includes important components, ingredients, properties and principles of operating the device, and copies of all applicable labeling.
  - Written procedures for monitoring the device and its safe use.
  - Names of other institutions which may take part in the investigation, as well as IRB information from the IRBs that have been or will be asked to review the study.
  - Any additional written reports on prior investigations conducted with the device.
  - FDA Form 1572 (or equivalent)
  - Sample Informed Consent Form (ICF) (disc or electronic)
  - Principal Investigator signed and dated CV (within 2 years)  On File
  - Principal Investigator current license  On File
  - Sub-investigator(s) signed and dated CV(s) (within 2 years)  On File
  - Copy of Massachusetts Research Registration  N/A
  - Site Information Form(s) *(a separate form is required for each facility to be used for this study)*
  - Completed subject compensation information as it will be stated in the ICF  N/A
  - Cooperative Review Form / Waiver of Review Form  N/A
  - Community Consultant Review Form (by request of IRB)  N/A
- Recruitment materials attached     Yes     No – *will be submitted at a later date*     N/A

Form Completed by:

\_\_\_\_\_  
Name (Printed)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Telephone Number

\_\_\_\_\_  
E-mail