

Initial Device Study Application (Sponsor/CRO – Multicenter Study)

Page 1 of 5

To be completed and submitted by Sponsor / CRO with initial multicenter protocol submission

SECTION 1: GENERAL STUDY INFORMATION

a. Sponsor: _____ b. Protocol Number: _____

c. Study Title: _____

SECTION 2: TEST ARTICLE INFORMATION

a. Test Article Name: _____

b. Please check the appropriate box(es):

- The device is FDA-approved for the indication in this study.
 510k clearance or PMA determination from the FDA – *attach a copy of an FDA-generated letter*
 The device is not FDA-approved or the study involves the investigational use of an FDA-approved device.

c. If the device is not FDA-approved or the study involves the investigational use of an FDA-approved device, please check the appropriate box:

- This study has a valid IDE # issued by the FDA – *please note the following instructions:* IDE #: _____

Please support your IDE # by submitting one of the following: (1) the Sponsor protocol with the IDE # on it; (2) a letter from the Sponsor; (3) a letter from the FDA.

- The device fulfills the requirements for an abbreviated IDE – *please attach a letter from the Sponsor (on letterhead) stating why this device is classified as Non-Significant Risk in accordance with 21 CFR 812.3(m).*

- The device does not require an IDE from the FDA for the following reasons:

This study an *In Vitro Diagnostic Device (IVD)* 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.

d. Does the device involve the use of ionizing radiation or isotopes?

- No Yes

e. Will the Sponsor be charging the Principal Investigator and/or subjects for the device?

- No Yes – *please attach a rationale and a description of the amount to be charged to PIs and/or subjects.*

SECTION 3: IRB REVIEW INFORMATION

Has this study ever been submitted to another IRB for review?

- Yes - *list the name of the IRB(s) and the outcome of the review(s) on a separate page.*
 No

SECTION 4: SPONSOR INFORMATION

Contact Person: _____

Company: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____ Fax Number: _____ Email: _____



**Initial Device Study Application
(Sponsor/CRO – Multicenter Study)
Page 2 of 5**

SECTION 5: CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION		<input type="checkbox"/> None
Contact Person: _____		
Company: _____		
Address: _____		
City: _____ State: _____ Zip Code: _____		
Phone Number: _____ Fax Number: _____ Email: _____		
SECTION 6: CONTACT INFORMATION		
Please indicate the name of the contact person to be copied on all IRB correspondence to sites:		
Name: _____ Company: _____		
SECTION 7: MAIL DELIVERY INFORMATION		
<i>NOTE: All documents will be delivered via First Class US Mail unless otherwise instructed.</i>		
a. Would you prefer overnight courier delivery of approval documents?		
<input type="checkbox"/> No – go to SECTION 8 <input type="checkbox"/> Yes – complete remainder of SECTION 7		Is this same method to be used for site documents?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Service Provider: <input type="checkbox"/> FedEx <input type="checkbox"/> DHL <input type="checkbox"/> UPS <input type="checkbox"/> Other:		
c. Account Number: _____ Reference Number: _____		
SECTION 8: BILLING INFORMATION		
<i>Please provide the correct name and address of the person who will be responsible for payment of services rendered.</i>		
<input type="checkbox"/> Same as Sponsor <input type="checkbox"/> Same as CRO <input type="checkbox"/> Other: _____		
Contact Person: _____		
Company: _____		
Address: _____		
City: _____ State: _____ Zip Code: _____		
Phone Number: _____ Fax Number: _____ Email: _____		
<i>NOTE: Any changes to the above information must be emailed to Michele@aspire-irb.com</i>		
SECTION 9: FUNDING INFORMATION		
Is this study federally-funded or subject to a federalwide assurance (FWA)?		
<input type="checkbox"/> Yes – please note that Aspire IRB does not accept federally-funded research or research that is subject to an FWA.		
<input type="checkbox"/> No		
SECTION 10: SITE INFORMATION		
a. How many <u>total</u> sites will be involved in this study? _____		
b. How many sites will be utilizing Aspire as their IRB? _____		
SECTION 11: 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: _____

**Initial Device Study Application
(Sponsor/CRO – Multicenter Study)
Page 3 of 5**

SECTION 11: SUBJECT ENROLLMENT INFORMATION (continued)

c. Please indicate whether the protocol design requires/includes the enrollment of any of the vulnerable populations listed below. Check all that apply. For all populations checked, please describe any additional safeguards included in the protocol to protect the rights and welfare of these subjects.

- | | |
|--|--|
| <input type="checkbox"/> Children / minors (<i>NOTE: 19 is the age of majority in Alabama and Nebraska; 21 is the age of majority in Puerto Rico.</i>) | <input type="checkbox"/> Employees of the PI/site and/or their immediate family members |
| <input type="checkbox"/> Pregnant women / fetuses | <input type="checkbox"/> Students of the PI/site |
| <input type="checkbox"/> Economically and/or educationally disadvantaged individuals | <input type="checkbox"/> Terminally ill individuals / individuals with life-threatening conditions |
| <input type="checkbox"/> Nursing home residents / institutionalized individuals | <input type="checkbox"/> Limited or non-readers / illiterate individuals |
| <input type="checkbox"/> Comatose individuals / traumatized individuals | <input type="checkbox"/> Hearing / visually impaired individuals |
| <input type="checkbox"/> Decisionally impaired individuals | |
| <input type="checkbox"/> Other (specify): | |
| <input type="checkbox"/> Non-English speaking individuals – <i>complete questions 1, 2 and 3 below.</i> | |
| 1. Would you like Aspire IRB to arrange for translation of the consent form(s)? | |
| <input type="checkbox"/> Yes | |
| <input type="checkbox"/> No | |
| 2. For which language(s) do you need the translation(s)? | |
| 3. Are there any additional items (e.g., recruitment materials, subject diaries) for which you would like Aspire IRB to arrange for translation? | |
| <input type="checkbox"/> Yes – <i>please list all items for which translation is requested:</i> | |
| <input type="checkbox"/> No | |
| <input type="checkbox"/> Do not anticipate the recruitment/enrollment of any subjects from vulnerable populations. | |

d. Will the use of Legally Authorized Representatives (LARs) be permitted in this study? Yes No

SECTION 12: SUBJECT RECRUITMENT METHODS

NOTE: All subject recruitment materials (including telephone screens) must be approved by the IRB prior to implementation.

Please indicate all anticipated subject recruitment methods:

- None Print Radio TV Newsletters Flyers Internet Other: _____

SECTION 13: CONFIDENTIALITY AND HIPAA INFORMATION

“Confidentiality” refers an individual’s wishes as to how his/her identifiable private information will be handled, managed, and disseminated. Confidentiality is a means of protecting that information, usually by safeguarding it from unauthorized disclosure.

- a. Please indicate any provisions included in the protocol 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.*

**Initial Device Study Application
(Sponsor/CRO – Multicenter Study)
Page 4 of 5**

SECTION 13: CONFIDENTIALITY AND HIPAA INFORMATION (continued)

- 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 Document.*
- d. If any of your study sites are covered entities, will you require a partial waiver of authorization in order to screen for the study?
 No Yes – *provide the IRB with your rationale for this need.*

SECTION 14: PRIVACY INFORMATION

“Privacy interests” refer to an individual’s interest in having control over the extent, timing, and circumstances of sharing oneself or information about oneself with others.

- a. Will personal information collected from subjects be limited to only that which is necessary for study purposes?
 No – *attach an explanation.* Yes
- b. Are there any additional provisions included in the protocol to protect the privacy of subjects?
 No Yes – *attach a description.*

SECTION 15: SITE MONITORING INFORMATION

Please indicate how sites will be monitored for this study (check all that apply)

- Telephone – frequency: _____
- Routine On-site Visits – frequency: _____
- For Cause On-site Visits – explain criteria for selection: _____
- Other – explain: _____

SECTION 16: DATA AND SAFETY MONITORING INFORMATION

Are there provisions in place for data and safety monitoring?

- No – *please provide a rationale explaining why such provisions are not necessary. Please note: studies determined to be more than minimal risk are required to have provisions in place for data and safety monitoring.*
- Yes – *please answer the following questions:*
- a. Who will monitor the data?
- b. What data will be monitored?
- c. How frequently will data be monitored?
- d. What analyses will be performed on the data?
- e. What decision rules (e.g., stopping rules) will be considered?

SECTION 17: ADVERSE DEVICE EFFECTS REPORTING

Adverse Device Effect Reports submitted by the Sponsor / CRO will be acknowledged to the main study file only. The Sponsor / CRO is responsible for providing copies of the acknowledged Adverse Device Effect Reports to individual sites.

OPTIONAL SERVICE:

For an additional fee, Aspire can provide site-specific acknowledgement letters for Adverse Device Effect Reports to each individual site. If you would like this optional service, please check here:

**Initial Device Study Application
(Sponsor/CRO – Multicenter Study)
Page 5 of 5**

SECTION 18: INITIAL STUDY CHECKLIST

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.

SECTION 19: SPONSOR/CRO AGREEMENT WITH ASPIRE IRB

On behalf of the Sponsor/CRO, I am requesting that Aspire IRB 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. On behalf of the Sponsor/CRO, I agree to promptly report any information that becomes available that may affect the safety of subjects, subjects' willingness to participate, or the IRB's approval to continue the study.

Authorized by:

<i>PRINTED NAME</i>	<i>SIGNATURE</i>	<i>DATE</i>
<i>TITLE</i>	<i>COMPANY</i>	
<i>TELEPHONE NUMBER</i>	<i>EMAIL ADDRESS</i>	