



INITIAL DEVICE STUDY APPLICATION – SPONSOR/CRO

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(to be completed / submitted by Sponsor / CRO with initial Multicenter protocol submission)

SECTION 1: GENERAL STUDY INFORMATION

- a. Sponsor: _____ b. Protocol Number: _____
c. Study Title: _____

SECTION 2a: 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 a FDA generated letter*)
- c. If the device is not FDA approved, please check the appropriate box:
 Proof of an FDA initiated IDE number: _____
(Please provide your IDE# or attach a FDA generated letter confirming that you have applied for an IDE)
 Letter from the Sponsor (*on letterhead*) stating why this device is classified as Non-Significant Risk in accordance with 21 CFR 812.3 (m)
- d. The device is does not require an IDE from the FDA for the following reasons:
 It is a low risk device that meets FDA exemption from premarket review
 It is 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.

SECTION 2b: ADDITIONAL CONSIDERATIONS

- a. Does the device involve the use of ionizing radiation or isotopes?
 No Yes
- b. Will the sponsor will be charging the Principal Investigator and / subjects for the device?
 No Yes - *If yes, attach a rationale and a description of the amount to be charged to PIs / subjects.*

SECTION 3: IRB REVIEW INFORMATION

- a. 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: _____

Aspire IRB, LLC (San Diego)
9320 Fuerte Dr., Suite 105
La Mesa, CA 91941
619.469.0108 (phone)
619.469.4108 (fax)

SECTION 5: CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION

None

Contact Person: _____
Company: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ FAX Number: _____ email: _____

SECTION 6: MAIL DELIVERY INFORMATION

Note: All documents will be delivered via First Class US Mail unless otherwise instructed.

- a. Would you prefer overnight courier delivery of approval documents?
 No – go to SECTION 7 Yes – complete remainder of SECTION 6 || Is this same method to be used for site documents?
 Yes No
- b. Service Provider: FedEx DHL UPS Other:
- c. Account Number: _____ Reference Number: _____

SECTION 7: BILLING INFORMATION

Please provide the correct name and address of the person who will be responsible for payment of services rendered

Same as Sponsor Same as CRO Other: _____
Contact Person: _____
Company: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ FAX Number: _____ email: _____

NOTE: Any changes to the above information must be emailed to Alycia@aspire-irb.com

SECTION 8: CONTACT INFORMATION

Please indicate the name of the contact person to be copied on all IRB correspondence to sites:

Name: _____ Company: _____

SECTION 9: SITE INFORMATION

- a. How many total sites will be involved in this study? _____
- b. How many sites will be utilizing Aspire as their IRB? _____

SECTION 10: 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: _____

SECTION 11: 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 12: 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 13: SAFETY MONITORING INFORMATION

Is there a Data Safety Monitoring Board (DSMB) for this study?

- No *If No, please indicate on a separate sheet the processes in place for reviewing Adverse Device Effects, identifying possible trends, and notifying the IRB and study investigators of these trends.*
- Yes *If Yes, please provide DSMB contact information and provide a copy of the DSMB Charter and/or the DSMB meeting schedule.*

DSMB CONTACT INFORMATION:

Contact Person: _____
 Address: _____

 City: _____ State: _____ Zip Code: _____
 Phone Number: _____ FAX Number: _____ email: _____

SECTION 14: ADVERSE DEVICE EFFECTS REPORTING

Adverse Device Effect Reports submitted by the site will be acknowledged to the site. It is the Principal Investigator's responsibility to file these events with the Sponsor and/or CRO.

OPTIONAL SERVICE:

For an additional fee, Aspire can provide site specific acknowledgement letters for receipt of Adverse Device Effects. If you would like this optional service, please check here:

SECTION 15: 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 16: Acknowledgement and 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.

Authorized by:

PRINTED NAME

SIGNATURE

DATE

TITLE

COMPANY

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TELEPHONE NUMBER

e-mail address