



Initial 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. Test Article Type: Drug Biologic Food / Drink Diagnostic Social / Behavioral

c. Does this study involve a radioactive drug?

Yes – please provide a copy of approval by a Radioactive Drug Research Committee.

No

d. Test Article Status: Marketed (and study does not involve investigational use)

Investigational – please note the following instructions: IND #: _____

Please support your IND # by submitting **one** of the following: (1) the Sponsor protocol with the IND # on it; (2) a letter from the Sponsor; (3) a letter from the FDA. If you have not obtained an IND #, please submit an explanation as to why not.

e. Study Phase: Phase I Phase II Phase III Phase IV Other: _____

SECTION 3: IRB REVIEW INFORMATION

Has this protocol been disapproved or terminated by another IRB prior to submission to Aspire IRB?

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: _____

SECTION 5: CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION

None

Contact Person: _____

Company: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____ Fax Number: _____ Email: _____

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

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

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

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 8 Yes – complete remainder of SECTION 7 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 8: 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 Michele@aspire-irb.com

SECTION 9: FUNDING INFORMATION

Is this study federally-funded or subject to a federalwide assurance (FWA)?

- Yes – please note that Aspire IRB does not accept federally-funded research or research that is subject to an FWA.
 No

SECTION 10: SITE INFORMATION

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

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

SECTION 11: SUBJECT ENROLLMENT INFORMATION (continued)

- Nursing home residents / institutionalized individuals Limited or non-readers / illiterate individuals
- Comatose individuals / traumatized individuals Hearing / visually impaired individuals
- Decisionally impaired individuals
- Other (specify):
- Non-English speaking individuals – *complete questions 1, 2 and 3 below.*
1. Would you like Aspire IRB to arrange for translation of the consent form(s)?
- Yes
- 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?
- Yes – *please list all items for which translation is requested:*
- No
- 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*
- c. Will you be submitting HIPAA language for review?
- No Yes – *submit as a separate HIPAA authorization form 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.*

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

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: IND SAFETY REPORTS

IND Safety 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 IND Safety Report to individual sites.

OPTIONAL SERVICE:

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

SECTION 18: INITIAL STUDY CHECKLIST

The following information must be included with your complete application by the submission deadline in order to be guaranteed placement on the agenda:

- Protocol supported by a valid IND # (if applicable)
- Investigator's Brochure (IND studies) *OR* Package Insert (FDA-approved drugs)
- Sample Informed Consent Document (disk / electronic)
- Other necessary information



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

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 IRB accepts responsibility for providing IRB oversight of this research. I understand that Aspire IRB has the right to conduct a site visit at any time 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, subject's willingness to participate, or the IRB's approval to continue the study.

Authorized by:

PRINTED NAME

SIGNATURE

DATE

TITLE

COMPANY

() -

TELEPHONE NUMBER

EMAIL ADDRESS