



INVESTIGATOR INITIAL STUDY APPLICATION (MULTICENTER STUDY)

Page 1 of 8

Answer each question completely. For those questions requiring additional explanation, 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.

SECTION 1: GENERAL STUDY INFORMATION

- a. Sponsor: _____ b. Protocol #: _____
- c. Protocol Title: _____
- d. Check the appropriate box and follow the instructions for completing each section of this form.
 Industry sponsored multicenter study, all protocol submission materials previously submitted by Sponsor / CRO

SECTION 2: PRINCIPAL INVESTIGATOR CONTACT INFORMATION

- a. Principal Investigator Name: _____
- b. Site Name: _____
Address: _____
City: _____ State: _____ Zip Code: _____
- c. Mailing Address – *should be the same as the address listed in Box #1 of FDA Form 1572 (if applicable)* Same as 2.a.
Address: _____
City: _____ State: _____ Zip Code: _____
- d. PI Phone Number: _____ PI FAX Number: _____
24-hour Phone Number to be listed in Informed Consent Document: _____
PI e-mail: _____
- e. Study Coordinator Name: _____
Business Phone Number: _____ FAX Number: _____
Study Coordinator e-mail: _____

SECTION 3: CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION

None

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

INVESTIGATOR INITIAL STUDY APPLICATION (MULTICENTER STUDY)

Page 3 of 8

SECTION 8: PRINCIPAL INVESTIGATOR (continued)

- k. Has the PI ever undergone a FDA/OHRP audit, received a FDA 483, Warning Letter or NIDPOE (*Notice of Initiation of Disqualification Proceedings and Opportunity to Explain*)?
 No Yes *–provide copies of all letters and correspondence* On File
- 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 No

SECTION 9: SUB-INVESTIGATORS

The following questions relate to Sub-investigators listed in Box #6 of the FDA Form1572.

If there are no Sub-investigators assisting the Principal Investigator with this study, 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 *–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 *–provide explanation* On File
- d. Has any Sub-investigator ever had an IRB impose any sanctions or restrictions on him/her?
 No Yes *–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 *–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 *–provide explanation* On File
- g. Has any Sub-investigator ever undergone a FDA/OHRP audit, received a FDA 483, Warning Letter or NIDPOE (*Notice of Initiation of Disqualification Proceedings and Opportunity to Explain*)?
 No Yes *–provide copies of all letters and correspondence* On File

**INVESTIGATOR INITIAL STUDY APPLICATION
(MULTICENTER STUDY)**

Page 4 of 8

SECTION 10: 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 –*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 –*explain how your site will manage the potential conflict of interest*

SECTION 11: SUBJECT RECRUITMENT

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

- a. 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) (*do not require IRB approval*) Other:
- b. Will you be using a centralized call service to screen callers?
 Yes - *submit telephone script and name of company / contact information.* No
- c. 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 12: COMPENSATION FOR PARTICIPATION

- a. Will study subjects be compensated for their participation in the study?
 Yes - *complete all of SECTION 10* No - *go to SECTION 11*
- 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 approximate value* No

INVESTIGATOR INITIAL STUDY APPLICATION (MULTICENTER STUDY)

Page 5 of 8

SECTION 13: 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

SECTION 14: 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 Per protocol

SECTION 15: VULNERABLE SUBJECTS

- a. Vulnerable subject populations must be provided with additional safeguards during the recruitment and consenting processes. Indicate whether any of the following vulnerable subject populations may be enrolled in this study.
- 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"/> Employees / Immediate family | <input type="checkbox"/> Students <input type="checkbox"/> Hearing / visually impaired |
| <input type="checkbox"/> Pregnant women / fetuses | <input type="checkbox"/> Life threatening condition / Terminally ill |
- Other (specify): _____
- Non-English speaking - *complete questions 1 & 2 below*
1. Do you require a translated consent form?
 Yes – *contact Aspire IRB upon receipt of your initial approval documents to request specified language*
 No
 2. Will there be someone available onsite to communicate with subjects in their primary language?
 Yes
 No - *explain how you plan to communicate with the subject during the consent process and subsequent study visits.*
- Do not anticipate the recruitment/enrollment of any subjects from vulnerable populations.
In the event that a subject from a vulnerable population presents him/herself as a potential study subject, the Board must 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.
- b. Has your site previously submitted a description of specific measures used to safeguard the vulnerable populations indicated above?
 Yes On File No - *attach specific safeguards at this time*



INVESTIGATOR INITIAL STUDY APPLICATION (MULTICENTER STUDY)

Page 6 of 8

SECTION 16: 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. 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 17: FEDERALLY FUNDED STUDIES

- a. Is this study federally funded? Yes No - go to SECTION 16
- Name of Federal Agency(ies): _____
- b. Did your site have to file a FWA with OHRP?
- No Yes - provide copies of your documentation.

SECTION 18: 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.**

NOTE: Any changes to billing information must be sent to Aspire IRB at Alycia@aspire-irb.com.



**INVESTIGATOR INITIAL STUDY APPLICATION
(MULTICENTER STUDY)**

Page 7 of 8

SECTION 1: INVESTIGATOR ACKNOWLEDGEMENT OF 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.
- 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 and IND Safety Reports promptly to the IRB.
- Report Serious Adverse Events and unanticipated problems involving risk to subjects or others that occur at my site within 5 calendar days from the date of discovery.
- Respond to all requests from the IRB in a timely fashion.
- Notify the IRB in writing when the study has closed.
- Agree to protect the rights, safety and welfare of the subjects to the best of my ability.

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 STUDY APPLICATION
(MULTICENTER STUDY)**

Page 8 of 8

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.

<input type="checkbox"/> Protocol Signature page for central IRB submission	
<input type="checkbox"/> Investigator Drug Brochure (IND Studies)	<input type="checkbox"/> N/A
<input type="checkbox"/> Package Insert (FDA approved drugs)	<input type="checkbox"/> N/A
<input type="checkbox"/> FDA Form 1572 (or equivalent)	
<input type="checkbox"/> Sample Informed Consent Form (ICF) (disc or electronic)	
<input type="checkbox"/> Principal Investigator signed and dated CV (within 2 years)	<input type="checkbox"/> On File
<input type="checkbox"/> Principal Investigator current license	<input type="checkbox"/> On File
<input type="checkbox"/> Copy of Massachusetts Research Registration	<input type="checkbox"/> N/A
<input type="checkbox"/> Sub-investigator(s) signed and dated CV(s) (within 2 years)	<input type="checkbox"/> On File
<input type="checkbox"/> Site Information Form(s) <i>(a separate form is required for each facility to be used for this study)</i>	
<input type="checkbox"/> Cooperative Review Form / Waiver of Review Form	<input type="checkbox"/> N/A
<input type="checkbox"/> Community Consultant Review Form (by request of IRB)	<input type="checkbox"/> N/A
<input type="checkbox"/> Completed subject compensation information as it will be stated in the ICF	<input type="checkbox"/> N/A
Recruitment materials attached <input type="checkbox"/> Yes <input type="checkbox"/> No – <i>will be submitted at a later date</i>	<input type="checkbox"/> N/A

Form Completed by:	
Name (Printed)	Date
Telephone Number	E-mail