

Initial Device Study Application (Investigator – Multicenter Study)

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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 Principal Investigator 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: _____

SECTION 2: PRINCIPAL INVESTIGATOR CONTACT INFORMATION

a. Principal Investigator (PI) Name: _____

b. Site Name: _____
Address: _____
City: _____ State: _____ Zip Code: _____

c. Mailing Address – *should be the same as the address listed in Box #1 of 1572 Equivalent* Same as 2.b.
Address: _____
City: _____ State: _____ Zip Code: _____

d. PI Phone Number: _____ PI Fax Number: _____
24-hour Phone Number to be listed in Informed Consent Document: _____
PI Email: _____

e. Study Coordinator Name: _____
Business Phone Number: _____ Fax Number: _____
Study Coordinator Email: _____

SECTION 3: CONTRACT RESEARCH ORGANIZATION (CRO) INFORMATION None

Contact Person: _____
Company: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ Fax Number: _____ Email: _____

SECTION 4: SITE MANAGEMENT ORGANIZATION (SMO) INFORMATION None

Contact Person: _____
Company: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ Fax Number: _____ Email: _____

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SECTION 5: MAIL DELIVERY INFORMATION

How would your site prefer to receive study documents? *(check one)*

- As per Sponsor / CRO instructions
 Regular Mail
 Overnight Courier Service *(account number required)*
 FedEx
 DHL
 UPS
 Other: _____ Account Number: _____

SECTION 6: 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 7: 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 8: PRINCIPAL INVESTIGATOR

If supporting documentation has been previously submitted to Aspire IRB, there is no need to re-submit. Simply check "Yes" and "On File". However, changes or new information must be submitted to Aspire IRB 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 *(attach copy)* Expiration Date: _____ N/A
- d. DEA Registration *(attach copy if applicable to this study)* Expiration Date: _____ N/A
- e. Has the PI's license ever been suspended, revoked, placed on probation or restricted?
 No Yes – *provide explanation* On File
- f. Have the PI's hospital privileges ever been suspended, revoked, placed on probation or restricted at any facility?
 No Yes – *provide explanation* On File
- g. Has the PI ever been charged with a misdemeanor or felony that relates to the practice of medicine?
 No Yes – *provide explanation* On File
- h. Has the PI ever had an IRB impose any sanctions or restrictions on him / her?
 No Yes – *provide explanation* On File
- i. Has the PI ever had an IRB terminate or suspend its approval of a study for any reason?
 No Yes – *provide explanation* On File
- j. Has the PI ever undergone a FDA/OHRP inspection, 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
- k. How long has the PI been conducting research? First study < 1 year 1-5 years > 5 years
- l. On how many studies is the PI current listed as the Principal Investigator? _____
- m. On how many studies is the PI current listed as a Sub-investigator? _____

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SECTION 8: PRINCIPAL INVESTIGATOR (continued)

- n. Has the PI attended any training specific to this study (e.g., Investigator Meeting, Site Initiation Visit or industry sponsored education)?
 Yes No – indicate the date the PI will complete this training: _____
- o. Principal Investigators are required to complete research-related training and/or education in the areas of Good Clinical Practice and protection of human research 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 1572 Equivalent.
 If there are no Sub-investigators assisting the Principal Investigator with this study, check N/A here and proceed go to SECTION 10.
 If supporting documentation has been previously submitted to Aspire IRB, there is no need to re-submit. Simply check "Yes" and "On File". However, changes or new information must be submitted to Aspire IRB in a timely manner.

- a. Please provide copies of all Sub-investigator qualifications (i.e., CVs, training, etc.) 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 an FDA/OHRP inspection, 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 – provide copies of all letters and correspondence On File

SECTION 10: STUDY STAFF

- a. How many key study staff members (e.g., PI, Sub-investigators, Coordinators) will assist in this study?
- b. Have all key study staff members completed research-related training and/or education in the areas of Good Clinical Practice and protection of human research subjects? Yes No
 Please attach a summary of training/qualifications of key study staff members, including protocol-specific training/education.

SECTION 11: CONFLICT OF INTEREST

"Immediate family members" include spouses or domestic partners, dependent children and minors, and anyone who resides with the investigator or who is the investigator's dependent for tax purposes.
 "Financial interest related to the research" means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

Please note: all amounts referenced below apply to aggregated financial interests of immediate family members.

- a. Does the PI, any Sub-investigator, member of the study staff and/or their immediate family members entered into any financial arrangements whereby the amount or value may be affected by the outcome of the study?
 No Yes – please explain how your site will manage the potential conflict of interest
- b. Does the PI, any Sub-investigator, member of the study staff and/or their immediate family members have any equity interest related to the research exceeding \$50,000 or 5% or greater interest in any single entity connected to the research? This includes, for example, any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices.
 No Yes – please explain how your site will manage the potential conflict of interest

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SECTION 11: CONFLICT OF INTEREST (continued)

- c. Does the PI, any Sub-investigator, member of the study staff and/or their immediate family members receive any payments exceeding \$25,000 (excluding the costs of conducting the study) from the study sponsor? This includes, for example, grant funding, compensation in the form of equipment, retainers, consulting fees, or honoraria.
 No Yes – *explain how your site will manage the potential conflict of interest.*
- d. Does the PI, any Sub-investigator, member of the study staff and/or their immediate family members have any proprietary interest related to the research? This includes, for example, a patent, trademark, copyright or licensing agreement.
 No Yes – *explain how your site will manage the potential conflict of interest.*
- e. Does the PI, any Sub-investigator, member of the study staff and/or their immediate family members have a board or executive relationship related to the research, regardless of the compensation?
 No Yes – *explain how your site will manage the potential conflict of interest.*
- f. Does the PI, any Sub-investigator, member of the study staff and/or their immediate family members have any potential conflicts of interest that are not outlined above that may interfere with or influence the conduct or outcome of the study?
 No Yes – *explain how your site will manage the potential conflict of interest.*

If any of the above information changes during the course of the study and for one year following study completion, Aspire IRB will need to be promptly notified.

SECTION 12: SUBJECT RECRUITMENT

Note: All subject recruitment materials must be approved by Aspire IRB 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 IRB 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 Telephone screening script
 Doctor to Subject Letters Doctor to Doctor Letters (*do not require IRB approval*) Other:
- b. Will you be using a centralized call service to screen callers?
 Yes – *please 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 – *please explain how you will maintain subject confidentiality.* No

SECTION 13: COMPENSATION FOR PARTICIPATION

- a. Will study subjects be compensated for their participation in the study?
 Yes – *complete all of SECTION 13* No – *go to SECTION 14*
- 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 subject 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 - *please provide an explanation and an approximate value* No

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SECTION 14: 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 15: 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 16: 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 at your site. *
- | | |
|---|---|
| <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"/> Pregnant women / fetuses
<input type="checkbox"/> Economically and/or educationally disadvantaged individuals
<input type="checkbox"/> Nursing home residents / institutionalized individuals
<input type="checkbox"/> Comatose individuals / traumatized individuals
<input type="checkbox"/> Terminally ill individuals / individuals with life-threatening conditions
<input type="checkbox"/> Other (specify): _____
<input type="checkbox"/> Non-English speaking individuals – <i>complete questions 1 & 2 below</i> | <input type="checkbox"/> Employees of the PI/site and/or their immediate family members
<input type="checkbox"/> Students of the PI/site
<input type="checkbox"/> Decisionally impaired individuals
<input type="checkbox"/> Limited or non-readers / illiterate individuals
<input type="checkbox"/> Hearing / visually impaired individuals |
|---|---|
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 – *Go to SECTION 17*
In the event that a subject from a vulnerable population presents him/herself as a potential study subject, Aspire IRB must be notified and provided with a description of the specific measures that will be used to safeguard the vulnerable subject during the consenting and enrollment processes.

***You must submit a description of specific measures used to safeguard the vulnerable populations indicated above**

- b. If children or minors will be enrolled, what is the legal age of consent to interventions or procedures associated with the research under state or local law? N/A
- c. Will children or minors without parents be enrolled?
 No Yes – *provide justification in terms of state law or a decision by legal counsel indicating who can consent on behalf of the child to general medical care under state or local law.*
- d. Will subjects with legally authorized representatives (LARs) be enrolled?
 No Yes – *provide justification in terms of state law or a decision by legal counsel of who constitutes an LAR in your state.*

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SECTION 17: 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. *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 provision 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 Document.*
- 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 18: 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. Will subjects’ personal information be collected in a private setting/location?
- No – *attach an explanation.* Yes – *attach a description of the setting/location.*
- c. Will study-related assessments and procedures be conducted in a private setting/location?
- No – *attach an explanation.* Yes – *attach a description of the setting/location.*
- d. Are there any additional provisions at your site to protect the privacy of subjects?
- No Yes – *attach a description.*

SECTION 19: BILLING INFORMATION

a. Bill Sponsor / CRO – *go to SECTION 20* **OR** Bill Principal Investigator (complete information below)

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 Michele@aspire-irb.com.

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SECTION 20: INVESTIGATOR AGREEMENT WITH ASPIRE IRB

As the Principal Investigator, I agree to uphold ethical standards and practices in research and conduct this research in accordance with applicable federal regulations, state and local laws, and requirements of Aspire IRB as follows:

- Conduct this study according to the approved protocol and in accordance with ICH Guidelines for Good Clinical Practice, 21 CFR Parts 50, 56, 312, and 812, and any additional conditions imposed by Aspire IRB or the FDA.
- Agree to protect the rights, safety and welfare of subjects to the best of my ability in accordance with the three ethical principles set forth in the Belmont Report: respect for persons, beneficence, and justice.
- 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 and Site Status Report Forms by their due dates.
- Report changes to the protocol without prior IRB approval to eliminate an apparent immediate hazard to subjects within 24 hours of implementation;
- Report the following occurrences within 5 calendar days from the date of discovery: serious adverse events; unexpected and related adverse events; and unanticipated adverse device effects.
- Report the following occurrences within 10 calendar days from the date of discovery: significant protocol deviations/violations; breaches of confidentiality; complaints from subjects when the complaints indicate unexpected risks or cannot be resolved by the research team; information that indicates a change to the risks or potential benefits of the research; findings or allegations of non-compliance; changes in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol; incarceration of a subject in a protocol overseen by Aspire IRB; events that requires reporting to the sponsor; sponsor-imposed suspensions for risk; FDA 483s, Warning Letters and/or other audit correspondence and my written response to the findings and corrective action (if applicable); any other audit report by a regulatory agency and/or sponsor or IRB; and any problem that I consider to be unanticipated and indicates that subjects or others are at increased risk of harm.
- Respond to all requests from Aspire IRB in a timely fashion.
- Notify Aspire 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 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.

My signature below indicates that I will comply with my responsibilities as Principal Investigator, as outlined above, for the protection of human subjects.

Principal Investigator Name (Printed)

Signature of Principal Investigator

Date

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INITIAL STUDY CHECKLIST

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

<input type="checkbox"/> Protocol Signature Page signed by the Principal Investigator	
<input type="checkbox"/> 1572 Equivalent	
<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"/> Sub-investigator(s) signed and dated CV(s) (within 2 years)	<input type="checkbox"/> On File
<input type="checkbox"/> Copy of Massachusetts Research Registration	<input type="checkbox"/> N/A
<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"/> Completed subject compensation information as it will be stated in the ICF	<input type="checkbox"/> N/A
<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
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