



ASENTRAL™ IRB STUDY APPLICATION FORM

Protocol Name: _____
Protocol Number: _____

Principal Investigator:	Contact Person:
Primary Site Name:	
Primary Site Address:	Address (If different):
Phone:	Phone:
FAX:	FAX:
E-mail:	E-mail:
List sub Investigators:	

Does this facility have an IRB? No Yes (If YES, please provide the following):

1. Letter from the appropriate facility authority indicating that the study may take place at this facility.
2. A letter from the facility IRB giving a waiver of jurisdiction.

Description of the facility where the study will take place:

Hospital
 Research Facility
 Clinic
 Private Practice
 Emergency Room
 Academic Setting
 Other (specify): _____

What is the nearest emergency facility to your site? Name of facility _____
Distance_(in miles) from your site _____

Is emergency equipment available at your site? No Yes (check all that apply)

Oxygen
 Crash Cart
 Defibrillator
 Other (specify): _____

Please Provide a signed, current Curriculum Vitae and Medical and Research Licenses for the Principal Investigator and all Sub-Investigators as well as a copy of the FDA form 1572 (if IND filed). Please provide previous clinical research experience of Principal Investigator (attach separate page if necessary or reference Curriculum Vitae if covered there): _____

1. Has this site been audited by the FDA or OHRP (OPRR) within the past three years?
 Yes No (If Yes, attach a summary of the audit findings and resolution)

2. Has another IRB ever suspended or terminated a study at this site?
 Yes No (If Yes, attach a summary)

3. Has this study ever been submitted to another IRB?
 Yes No If Yes, list the name and contact information of the IRB and attach a summary of their findings. _____

3. Has the Principal Investigator or any Sub-Investigator ever been disciplined by a medical/licensing board, or been convicted of a crime?
 Yes No (If Yes, attach a summary)

4. Has the Principal Investigator or any Sub-Investigator ever been disciplined by the FDA, OHRP, or by an IRB?
 Yes No (If Yes, attach a summary)

5. Does the Principal Investigator or any Sub-Investigator have a financial interest (other than study payment) in this study?
 Yes No (If Yes, attach a summary)

The Principal Investigator agrees to conduct the study in accordance with all federal, state, and local regulations, laws and/or statutes. Are you familiar with the laws governing research involving human subjects in your state/province?
 Yes No _____

Have the laws changed within the past year? Yes No

Please use this space to provide any additional information: _____

TRAINING AND QUALIFICATIONS

1. How much experience have you and your staff had conducting clinical research trials?

Principal Investigator: less than 1 year 1 to 2 years 3-5 years greater than 5 years

Sub Investigator(s)

Name: _____ < 1 yr 1-2 yrs 3-5 yrs > 5 yrs

Name: _____ < 1 yr 1-2 yrs 3-5 yrs > 5 yrs

Name: _____ < 1 yr 1-2 yrs 3-5 yrs > 5 yrs

Name: _____ < 1 yr 1-2 yrs 3-5 yrs > 5 yrs

Please attach additional page(s) if necessary.

Clinical Research Coordinator(s)

Name: _____ < 1 yr 1-2 yrs 3-5 yrs > 5 yrs

Name: _____ < 1 yr 1-2 yrs 3-5 yrs > 5 yrs

2. How many trials does your site conduct on an annual basis? _____

3. How many trials are you currently serving as the Principal Investigator for? _____

4. How many trials does the primary study coordinator for this study, have ongoing? _____

5. Is your staff (Principal Investigator, sub Investigators, and Clinical Research Coordinators) familiar and knowledgeable in FDA/Good Clinical Practices (GCP) and the Belmont Report?
 Yes No

Please check the type of research training that each of your primary research staff have received in the past.

	<u>Investigator</u> <u>Mtgs</u>	<u>OHRP</u>	<u>NIH Education</u>	<u>GCP</u>	<u>CITI</u>	<u>Other (specify)</u>
Principal Investigator:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Sub I's:						
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

	<u>Investigator</u> <u>Mtgs</u>	<u>OHRP</u>	<u>NIH Education</u>	<u>GCP</u>	<u>CITI</u>	<u>Other (specify)</u>
CRC's:						
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
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Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Name: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

6. Describe the type of **ongoing** education/training given to staff at site: _____

Will any satellite sites be used for recruitment, screening, treatment or follow-up for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, list below and Complete a "Satellite Site Form" for each)	
Site Address (1):	Site Address (2):
Phone:	Phone:
Contact Person:	Contact Person:
Site Address (3):	Site Address (4):
Phone:	Phone:
Contact Person:	Contact Person:

SUBJECT INFORMATION

1. How many subjects (#) do you plan to enroll at this site? _____
 Approximate % of Males: _____ Approximate % of Females: _____

2. What is the **approximate** ethnic makeup of the population from which subjects will be recruited for this research?
 _____ % African-American _____ % Pacific Islander _____ % Asian
 _____ % Caucasian _____ % Middle Eastern _____ % Native American
 _____ % Hispanic _____ % Other

3. Describe the local attitude toward research involving human subjects that might affect this study:
 Positive Negative
 If other than positive, please explain: _____

4. Will this study be recruiting subjects from any of the following vulnerable populations? No Yes
 Check all the categories that apply;

Minors: Age Range: _____ Employees Prisoners
 Nursing Home Residents Pregnant Women
 Seriously/Terminally Ill Mentally Impaired Economically Disadvantaged

Additional regulations apply to vulnerable subject populations. Provide a brief summary of special considerations/additional procedures that will be employed to ensure the protection of these subjects. (For example, screening to ensure that the subject has the capacity to consent, or if the subjects will be given additional time to consider participating, etc.). _____

5. Which categories of subjects will be recruited for this study? (check all that apply)

Out-Patient In-Patient Private Practice Subjects General Population
 Other. Please explain: _____

6. How do you intend to recruit subjects for this research study?

From existing Subjects From referrals Other (specify): _____

Using Subject Recruitment Materials (IRB approval required)
 Newspaper Radio Flyers Letters to subjects Phone Screen
 Television Bulletin Boards Internet Public Service Announcements
 Other (specify): _____

7. Are recruitment materials (e.g., advertisements, posters, brochures, etc.) included in this submission?
 Yes No

8. Do you intend to pay subjects for participation (including all types of reimbursement, such as parking and/or travel costs)? No Yes (check all that apply)

Cash Check Gift Certificate Other (specify): _____

Total Amount: \$ _____ Prorated as follows: _____

When will subjects be paid?
 At each visit At study completion Other (specify): _____

INFORMED CONSENT PROCESS

1. Who will discuss the study information and Consent Form with the subject for this research study?
 Investigator Sub-Investigator Research Coordinator(s) Other (specify): _____

2. Will Social Security numbers, subject's names, hospital record numbers, or any other identifier (other than subject initials and study number) be sent off-site?
 No Yes (explain) _____

3. Will subjects who do not understand English be enrolled in the study?
 No Yes, and the consent form needs to be translated into the following languages: _____

Spanish Portuguese Russian French/Creole Other(specify): _____

4. Please attach a copy of your site's Informed Consent Process SOP (Standard Operating Procedure) **OR** provide brief answers to each question below. **SOP attached**

- A. When will subjects be consented? _____
- B. Where will subjects be consented? _____
- C. How much time is spent (initially) discussing the study with each subject? _____
- D. How much time will subjects be given to consider their decision to participate? _____
- E. Are subjects encouraged and given time to discuss the study with family members?
 Yes No If no, why not? _____
- F. Will a copy of the informed consent form be given to the subject to take home with them?
 Yes No If no, why not? _____
- G. Which members of the research staff will be available to answer questions? _____
- H. Does the person obtaining the consent explain the risks of the study, the subject's right to decide not to participate, and the subject's right to withdraw from the study at any time? _____
- I. What is the specific education, experience and research training of the person(s) conducting the Informed Consent Process? _____

SPONSOR INFORMATION

Contact Name (CRA or Project Manager):	
Company	
Address	
City, State, Zip	
Telephone	
Fax	
E-mail	

CRO (Contact Research Organization) INFORMATION

Contact Name (CRA or Project Manager):	
Company	
Address	
City, State, Zip	
Telephone	
Fax	
E-mail	

INVESTIGATOR AGREEMENT

- *I certify that the information contained above is accurate. I acknowledge the Asentral Institutional Review Board (Asentral) has the authority to oversee this study and suspend the study if necessary to protect the rights and welfare of the study subjects. I agree to provide Asentral with the information they require to conduct initial and continuing review of this study on a timely basis and that if the information is not provided, Asentral may suspend the study.*
- *I agree not to make changes in the research protocol without prior written approval from Asentral. Furthermore, I will report all changes in research activities and unanticipated problems involving risks to research subjects or others.*
- *I agree not to use any informational materials regarding the study that involve the subjects or potential subjects, without prior IRB approval (for example, advertising, patient recruitment materials, gifts, patient handouts, diaries, questionnaires, etc.).*
- *I agree to abide by all my responsibilities as outlined in the Code of Federal Regulations and ICH Guidelines and to be aware of and abide by, all state and local rules, regulations, statutes and laws.*
- *I also agree that either I, or someone under my supervision, will verbally explain the Subject Information and Consent Form to all prospective research subjects and obtain their signature on the form prior to performing any research study procedures. A copy of the signed and dated Subject Information and Consent Form will be given to the research subject for his or her records.*
- *I understand that the Asentral IRB has the right to visit my research study site(s) at any time, with appropriate notice.*
- *I understand that the falsification of information provided to the Asentral IRB may result in sanctions by the IRB and a notification to my state medical licensing board or other appropriate authorities.*

Signature of the Principal Investigator

Date

Printed/Typed Name of the Principal Investigator