



ASENTRAL™ IRB

SATELLITE SITE APPLICATION FORM

Protocol Number: _____
Principal Investigator: _____

Satellite Site Name:	Contact Person:
Satellite Site Address:	Phone:
	FAX:
	E-mail:

<p>For what purposes will the satellite site be used?</p> <p><input type="checkbox"/> Recruitment <input type="checkbox"/> File Storage <input type="checkbox"/> Study Procedures <input type="checkbox"/> Other. Please explain</p>
<p><input type="checkbox"/> The Principal Investigator will be working out of this satellite site</p> <p><input type="checkbox"/> The following Sub-investigator(s) will be working out of this satellite site: _____</p>
<p>What is the nearest emergency facility to your site? Name of facility _____ Distance_(in miles) from your site _____</p> <p>Is emergency equipment available at your site? <input type="checkbox"/> No <input type="checkbox"/> Yes (check all that apply)</p> <p><input type="checkbox"/> Oxygen <input type="checkbox"/> Crash Cart <input type="checkbox"/> Defibrillator <input type="checkbox"/> Other (specify): _____</p>
<p>Does this facility have an IRB? <input type="checkbox"/> No <input type="checkbox"/> Yes (If YES, please provide the following):</p> <ol style="list-style-type: none"> 1. A 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.
<p>Will study medication be stored and dispensed at this satellite site?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Has this site ever been audited by the FDA or OHRP (OPRR)?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, attach a summary of the audit findings and resolution)</p>

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Has another IRB ever suspended or terminated a study at this site?

Yes No (If Yes, attach a summary)

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 at this site?

% African-American

% Pacific Islander

% Asian

% Caucasian

% Middle Eastern

% Native American

% Hispanic

% Other

3. Who will discuss the study information and Consent Form with the subject for this research study?

Investigator Sub-Investigator Research Coordinator(s)

Other (specify): _____

4. Will subjects who do not understand English be enrolled in the study at this site?

No Yes, and the consent form needs to be translated into the following languages:

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

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 medical research in your state/province?

Yes No _____

Have the laws changed within the past year? Yes No If yes, please explain:

Please use this space to provide any additional information: _____

Signature of the Principal Investigator or Designee

Date

Printed/Typed Name of the Principal Investigator or Designee