



SITE INFORMATION FORM

Page 1 of 3

This form must be completed for EACH site where your study will be conducted as listed in Boxes #1 and #3 of the FDA Form 1572. Submission of this form is required before any studies at your facility can be considered for approval. This form must be updated and submitted every two years.

Completion Date:

Site Name: _____

Address: _____

City: _____

State: _____

Zip Code: _____

Contact Person: _____

Phone No.: _____

FAX No.: _____

Please indicate whether this is a NEW Site Information Form or an UPDATED Site Information Form.

New Site Information Form Updated Site Information Form

SECTION 1: RESEARCH SITE INFORMATION

HIPAA Statement: If this site is considered a "covered entity" 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 site are HIPAA compliant.

a. Describe this site / facility:

- Private / group practice Research facility Surgery center Hospital
 Long-term care facility University / Academic Medical Center
 Other – specify: _____

b. Is this site under the jurisdiction of a local IRB? No Yes – documentation of local IRB Waiver required

c. How long has this site been conducting research? _____

d. How many studies have been conducted at this site in the past year? _____

e. What is the total number of research staff at this site? _____

f. What study activities will be conducted at this site / facility? – check all that apply:

- Administrative activities Informed Consent discussion Study Visits
 Specific procedures only (list here): _____

g. List any specialized equipment available at the site for specialized study related procedures: _____

h. How often does the Principal Investigator see study subjects? – check all that apply:

- First Visit All Visits Last Visit As mandated by protocol
 Only when requested Other - specify: _____

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

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Page 2 of 3

SECTION 2: EMERGENCY MEASURES

- a. Indicate the emergency equipment on site to manage serious adverse events or life threatening situations:
- CPR certified personnel
 Benadryl
 Epinephrine
 Oxygen
 911
 Defibrillator / AED
 Crash Cart - *workstation including drugs, supplies and equipment used for the medical purpose of treating cardiopulmonary emergencies.*
 Other - *specify:* _____
- b. What is the site's proximity to closest ER?
- Onsite
 less than 1 mile
 1 - 4 miles
 5 - 10 miles
 more than 10 miles

SECTION 3: 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 4: INFORMED CONSENT PROCESS

Informed consent is a process, which takes place before, during and after the study. Subjects must read and sign the consent form before any study-related procedures are performed. It is the responsibility of the principal investigator to oversee the informed consent process and ensure that the contents of the Informed Consent Form are orally presented to each subject. Personnel involved in the Informed Consent process must be qualified to address the concerns of potential subjects.

- a. Who is authorized to conduct the Informed Consent discussion with potential study subjects at this site?
– check all that apply
- Principal Investigator
 Subinvestigator(s)
 Study Coordinator(s)
 Other (specify): _____
- b. Is the Principal Investigator available to answer questions that from potential study subjects during the Informed Consent discussion?
- Yes
 No – *provide an explanation as to why not*
- c. Describe your process for obtaining informed consent from potential study subjects - *attach separate sheet of paper if necessary.*
- d. Are subjects allowed to:
- a. Take the consent home before deciding to participate in a study?
 Yes
 No
 b. Take as long as needed to decide whether or not to participate in a study?
 Yes
 No



SITE INFORMATION FORM

Page 3 of 3

Name of Person Completing this Form

Date

Signature of Person Completing this Form

Signature of Principal Investigator

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