

## 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 Form FDA 1572. Submission of this form is required before any study at your site(s) can be considered for approval. This form must be updated and submitted every two years.***

Completion Date: _____
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**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 – *please specify:* \_\_\_\_\_
- b. Is this site under the jurisdiction of a local IRB?     No     Yes – *documentation of local IRB Waiver required*
- c. The IRB must confirm the Principal Investigator has permission from the site to conduct study activities. Indicate:
- A letter from the site granting the Principal Investigator permission to conduct study activities is attached.
- N/A – the Principal Investigator is responsible for authorizing whether study activities can be conducted at this site.
- d. How long has this site been conducting research? \_\_\_\_\_
- e. How many studies have been conducted at this site in the past year? \_\_\_\_\_
- f. What is the total number of research staff at this site? \_\_\_\_\_
- g. 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): \_\_\_\_\_
- h. List any specialized equipment available at the site for specialized study related procedures:
- \_\_\_\_\_
- i. 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:* \_\_\_\_\_

**\*Please complete Waiver/Deference of Review Form**

## SITE INFORMATION FORM

*Page 2 of 3*

### SECTION 2: EMERGENCY MEASURES

- a. Indicate the emergency equipment on site to manage serious adverse events, life threatening situations, or other consequences of participation in the research:
- 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.*  
 Counseling or other psychosocial support  
 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 Document 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 Consent Document 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   
  Sub-investigator(s)   
  Study Coordinator(s)  
 Other (specify): \_\_\_\_\_
- b. Is the Principal Investigator available to answer questions 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 a separate sheet of paper if necessary.*
- d. Are subjects allowed to:
1. Take the consent home before deciding to participate in a study?       Yes     No
  2. Take as long as needed to decide whether or not to participate in a study?       Yes     No
  3. Ask questions and have questions answered?       Yes     No

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## SITE INFORMATION FORM

*Page 3 of 3*

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Name of Person Completing this Form

Date

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Signature of Person Completing this Form

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Signature of Principal Investigator