

**Goodwyn Institutional Review Board, Ltd**  
**New Site Location Questionnaire**

Principal Investigator: \_\_\_\_\_

Contact for additional information about this report: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

**(If the primary address has changed, indicate the previous primary address here)**

Site Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

Street Address (2): \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Site Phone: \_\_\_\_\_ Site Fax: \_\_\_\_\_

**Scope**

1. Is this a change of address for your primary facility:  Yes  No

2. Is this an additional research location where you may conduct all research regardless of protocol:  Yes  No

3. List the protocol numbers and sponsors of the studies in which this change in location will apply:  Yes  No

Protocol Number: \_\_\_\_\_

Sponsor: \_\_\_\_\_

**Study Personnel**

4. Are there any changes in study personnel?  Yes  No

If **yes**, please attach a completed Personnel Update form.

**Vulnerable Populations**

5. Will you enroll subjects at your new/additional site from any of these vulnerable groups (check all that apply):

- Adults with diminished decision-making capability.
- Children / Minors
- Economically disadvantaged
- Illiterate / Educationally disadvantaged
- Physically Handicapped
- Pregnant women
- Prisoners
- Sponsor/site employees or their family members
- Not Applicable

(The measures outlined in the *Principal Investigator Responsibilities Handbook* must be employed for these populations.)

**Involvement of Other IRBs**

6. Is your new location under the jurisdiction of another IRB:  Yes  No

If **yes**, please attach documentation of deferral of jurisdiction to Goodwyn IRB

**Potential Change to Consent Document**

7. Will the new location require an update to the telephone number(s) in your current informed consent document:  Yes  No

If **yes**, please provide the following:

New Phone: \_\_\_\_\_

New Emergency/After-Hours Phone: \_\_\_\_\_

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**Non-English Speaking Subjects**

8. Will you enroll non-English speaking subjects at the new/additional site:  Yes  No
- If **yes**, specify language: \_\_\_\_\_
- If **yes**, will you have someone at your new/additional site who is capable of answering questions in their language and who is available to them during the study:  Yes  No
- If **yes**, will a native speaking advocate or family member be available at the time of consent to answer any questions for the non-English speaking subjects:  Yes  No

**New Location Address, Phone and Description**

9. Provide the below information for the new research location.

Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

Street Address (2): \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_

Facility Description (check one):  Administrative (records only, no study procedures performed here).  
 Private/hospital/clinic office where study visits will be conducted.  
 Research only office where study visits will be conducted  
 Testing center only (i.e. Radiology, Phlebotomy).  
 Residential facility

Covered Entity (under HIPAA)  Yes  No Distance to a Hospital: \_\_\_\_\_

911 Response time: \_\_\_\_\_ Name of the Hospital: \_\_\_\_\_

Emergency Equipment: (check all that apply)

<input type="checkbox"/> CPR Certified Individual on Premises	<input type="checkbox"/> Defibrillator
<input type="checkbox"/> Oxygen	<input type="checkbox"/> IV Equipment
<input type="checkbox"/> Ambu Bag	<input type="checkbox"/> None
<input type="checkbox"/> Oral / Nasal Airways	<input type="checkbox"/> Other
<input type="checkbox"/> Intubation Equipment	

Emergency Medications: (check all that apply)

<input type="checkbox"/> Epinephrine	<input type="checkbox"/> Glucose (oral, fast-acting)
<input type="checkbox"/> Diphenhydramine (Benadryl)	<input type="checkbox"/> Glucose (IV – D50)
<input type="checkbox"/> Glucagon (IM or IV)	<input type="checkbox"/> None
	<input type="checkbox"/> Other

If you checked "other" in your response above, please describe the additional equipment / medications: \_\_\_\_\_

**Confidentiality of Study Records**

10. Describe provisions made at your new/additional site(s) to maintain confidentiality of clinical study records (check all that apply):
- Only authorized personnel have access to the study records.
  - Study records are kept in a secure area
  - Study Records are maintained after study termination with the same degree of security
  - Study records are stored separately from other medical records
  - Other: \_\_\_\_\_

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**State and Local Laws**

11. Are there any state or local regulations/laws that have an impact on this research study at the new location? (If you are uncertain, please contact your legal counsel.):

Yes  No

If **yes**, please summarize: \_\_\_\_\_

This Application for approval to enroll human subjects in research conducted at the site(s) described above requires the assurances and signature(s) indicated below.

**The PI must use measures to protect vulnerable populations, including any patient for which the PI is also the P Care Provider, as outlined in the "[Principal Investigator Responsibilities Handbook](#)."**

The undersigned acknowledges and accepts responsibility for assuring adherence to federal and state regulations, and organizational policies governing the protection of human subjects in research at all research locations represented in this document.

Your signature also indicates an acknowledgment and agreement that: correspondence and notifications from Goodwyn Institutional Review Board, Ltd. (Goodwyn IRB) may be generated and signed in electronic form; you will receive hard copy (printouts) of such electronic documents; and any such printouts accurately reflect the electronic original. All such printouts shall be treated in all ways as originals.

A photostatic or facsimile copy of this document is as valid as the original and shall be conclusive evidence of the original by the undersigned. The undersigned declare that the above statements and representations are true and correct and that no facts have been suppressed or misstated.

**Signature of Principal Investigator:**

\_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_