

Goodwyn Institutional Review Board, Ltd.

**UPDATE: RESEARCH SITE APPLICATION
New Site Location Questionnaire**

Name of Principal Investigator:

Name of Research Coordinator:

**Site Name and
Address:**

**New Site Name and
Address:**

*(If the primary site address
has changed)*

Site Phone:

Site Fax:

Email:

If you need additional space to respond to a question, please use another sheet.

<p>1. Are there any changes in study personnel? If yes, please provide Curriculum Vitae and updated Form 1572 as appropriate.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>2. Describe the new location: <input type="checkbox"/> Hospital <input type="checkbox"/> University <input type="checkbox"/> Private practice (indicate specialty: _____) <input type="checkbox"/> Clinic connected to a hospital <input type="checkbox"/> Free-standing clinic</p>	
<p>3. Is your new location under the jurisdiction of another IRB? If yes, the IRB Chairman or administrative official must provide a letter authorizing Goodwyn IRB's review and oversight for the particular study(ies).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>4. Are there any strong demographic, religious or cultural attitudes in your community/research site that would impact the conduct of this study? If yes, please describe:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>5. Will this new location require an update to the telephone number(s) in your current informed consent document? If yes, please provide the following: New Phone: New Emergency/After-Hours Phone (if different than above):</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. VULNERABLE POPULATIONS	
<p>6a. Will you enroll children/minors at the new location? If yes, answer the following questions.</p> <p>Do you have experience with pediatric subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Under your state and local law, what is the age of consent: _____</p> <p>Under your state and local law, who is authorized to consent on behalf of minors to general medical care ("Guardians")? _____</p> <p>Will you follow the expected safeguards noted below? (If no, attach a letter of explanation.)</p> <ul style="list-style-type: none"> • Parental permission and assent will be obtained as required by Goodwyn IRB. • The site will verify any state law restrictions on the use and authority of guardians in research by consulting with legal counsel. • If emancipated minors are enrolled without parental permission, the site will contact Goodwyn IRB to obtain appropriate consent process and further consideration of appropriate safeguards. 	<input type="checkbox"/> Yes <input type="checkbox"/> No

<p>6b. Will you enroll Sponsor or site employees or their family members at the new location? If yes, answer the following question.</p> <p>Will you follow the expected safeguards noted below? (If no, attach a letter of explanation.)</p> <ul style="list-style-type: none"> • Such prospective subjects may receive a broad invitation to participate, but will not be approached directly. • The informed consent process will not be administered by an individual in a supervisory position over the prospective subject. 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>6c. Will you enroll illiterate or educationally disadvantaged subjects (other than young children) at the new location? If yes, answer the following question.</p> <p>Will you follow the expected safeguards noted below? (If no, attach a letter of explanation)</p> <ul style="list-style-type: none"> • A witness not involved with the research will be present during the consent process to attest to the accuracy of the presentation and the apparent understanding of the prospective subject. • The prospective subject will be asked to “make their mark.” 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>6d. Will you enroll non-English speaking subjects at the new location? If yes, specify language(s): _____.</p> <p>You must have a translated consent or information sheet approved before using it. If you need assistance in preparing or certifying translations of your consent documents, call Goodwyn IRB at (513) 793-8900.</p> <p>If non-English speaking subjects are enrolled do you have someone at your site who is capable of answering questions in their language and who is available to them during the study? If no, describe your mechanism for answering questions for these non-English speaking subjects:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>6e. Will you enroll adults with diminished decision-making capacity at the new location? If yes, complete the Supplemental Study Documents and Procedures form and answer the following questions.</p> <p>Under your state and local law, who is authorized to consent on behalf of a prospective subject to his or her participation in the procedures involved in research (“Legally Authorized Representative”)? _____</p> <p>Will you follow the expected safeguards noted below? (If no, attach a letter of explanation)</p> <ul style="list-style-type: none"> • The determination of capacity will not be subjective, but will be based on the procedure described in your Supplemental Study Documents and Procedures form or required by Goodwyn IRB. • Consent will be obtained from a legally authorized representative (LAR). • If surrogate consent is required from LARs, the site will verify any state-law restrictions on the use of LARs in research by consulting with local legal counsel. • Prospective subject will be given additional time to ask questions; and • The prospective subject will not participate in the study unless s/he provides ongoing affirmative assent. 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
<p>6f. Will you enroll pregnant women at the new location? If yes, answer the following question.</p> <p>Will you follow the expected safeguards noted below? (If no, attach a letter of explanation)</p> <ul style="list-style-type: none"> • Discuss possible risks to the woman and fetus during the consent process. 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No

6g. Will you enroll economically disadvantaged subjects at the new location? Yes
 If yes, answer the following question. No

Will you follow the expected safeguards noted below? (If no, attach a letter of explanation) Yes
 No

- Set compensation and other inducements at a level that is not coercive.
- Prorate compensation.
- Pay before your designated time period if requested.

6h. Will you enroll subjects from any of the following additional groups at the new location? Yes
 If yes, please check all that apply: No

Military Personnel (Active Duty & Reserve) Life Threatening Condition Prisoners
 Seriously Debilitating Illness/Disease Physically handicapped

If yes, detail the additional safeguards you use to protect the rights and welfare of these subjects, including accommodations for informed consent process (use a separate page if necessary).

7. You must provide information for each new/additional location where subjects will be seen.
 (Locations must match those listed on associated FDA Form 1572, if required.) Attach additional pages if needed.

Location #1	Location #2	Location #3
Street address and City:	Street address and City:	Street address and City:
Covered entity under HIPAA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Covered entity under HIPAA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Covered entity under HIPAA? <input type="checkbox"/> Yes <input type="checkbox"/> No
How close is this location to a hospital with emergency facilities?	How close is this location to a hospital with emergency facilities?	How close is this location to a hospital with emergency facilities?
Name of the hospital:	Name of the hospital:	Name of the hospital:
911 response time:	911 response time:	911 response time:
Emergency equipment: (check all that apply)	Emergency equipment: (check all that apply)	Emergency equipment: (check all that apply)
<input type="checkbox"/> CPR certified staff <input type="checkbox"/> Oxygen <input type="checkbox"/> Ambu bag <input type="checkbox"/> Airways (check all that apply) <input type="checkbox"/> Oral/Nasal airways <input type="checkbox"/> Intubation Equipment <input type="checkbox"/> Other (describe): <input type="checkbox"/> Defibrillator <input type="checkbox"/> IV Equipment <input type="checkbox"/> Medications: <input type="checkbox"/> Epinephrine <input type="checkbox"/> Diphenhydramine <input type="checkbox"/> Glucagon <input type="checkbox"/> Glucose <input type="checkbox"/> Other: <input type="checkbox"/> Other (describe):	<input type="checkbox"/> CPR certified staff <input type="checkbox"/> Oxygen <input type="checkbox"/> Ambu bag <input type="checkbox"/> Airways (check all that apply) <input type="checkbox"/> Oral/Nasal airways <input type="checkbox"/> Intubation Equipment <input type="checkbox"/> Other (describe): <input type="checkbox"/> Defibrillator <input type="checkbox"/> IV Equipment <input type="checkbox"/> Medications: <input type="checkbox"/> Epinephrine <input type="checkbox"/> Diphenhydramine <input type="checkbox"/> Glucagon <input type="checkbox"/> Glucose <input type="checkbox"/> Other: <input type="checkbox"/> Other (describe):	<input type="checkbox"/> CPR certified staff <input type="checkbox"/> Oxygen <input type="checkbox"/> Ambu bag <input type="checkbox"/> Airways (check all that apply) <input type="checkbox"/> Oral/Nasal airways <input type="checkbox"/> Intubation Equipment <input type="checkbox"/> Other (describe): <input type="checkbox"/> Defibrillator <input type="checkbox"/> IV Equipment <input type="checkbox"/> Medications: <input type="checkbox"/> Epinephrine <input type="checkbox"/> Diphenhydramine <input type="checkbox"/> Glucagon <input type="checkbox"/> Glucose <input type="checkbox"/> Other: <input type="checkbox"/> Other (describe):
<input type="checkbox"/> None - Administrative Site Only	<input type="checkbox"/> None - Administrative Site Only	<input type="checkbox"/> None - Administrative Site Only

8. Describe provisions made at your new site 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 stored separately from other medical records.
- Study records are maintained after study termination with the same degree of security.
- Other (please describe):

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 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: _____

Completed application forms should be sent to:
Goodwyn Institutional Review Board, Ltd.
9380 Main Street
Cincinnati, OH 45242
Fax: 513-793-2800 or 513-793-4800