

**Goodwyn Institutional Review Board, Ltd.**

**Modification Request**

**Sponsor:**

**Protocol Number:**

**Modification being**

**submitted on behalf of:**  **All Active Investigators**  
 **An Individual Principal Investigator**  
**(PI's name):**

Check type of Change:

**Procedures:** Briefly summarize proposed changes below. Assess impact on risk level. If you are the study sponsor, submit a copy of the modified/amended protocol.

**Investigator Brochure Update:** Identify and summarize the information that has changed or is being added. Submit a copy of the updated Brochure or brochure amendment.

**Investigators/Study Personnel:** List the new investigators/study personnel below. Submit a curriculum vita for each added sub-investigator, study coordinator or other personnel. If the modification proposes a new Principal Investigator (PI), attach a curriculum vita and a copy of the PI's medical license. If a new PI is proposed, you must also complete and submit a New Principal Investigator form.

(Please list new investigators below)

Name	Role *	Delegated Responsibility(ies) in this Study	Training ** (check all that apply)
			<input type="checkbox"/> 1** <input type="checkbox"/> 2** <input type="checkbox"/> 3**
			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3

\* Sub-investigator, Research Coordinator, Pharmacist, etc.

\*\* 1 = Completion of the CITI Program: Course in the Protections of Human Research Subjects  
2 = Completion of the National Institutes of Health (NIH) Clinical Center: Clinical Research Training  
3 = Training/Review of the FDA Information Sheets, GCP Guidelines, and the Belmont Report

**Patient Recruitment:** Submit completed New Recruitment Materials/Methods form and any new or revised recruitment materials.

**Site Status:** When changing information about a site, or adding a site location, complete and submit a New Site Location form. If corollary changes are required in the consent, please also check "Consent Form Modification" below.

**Consent Form Modification:** Submit proposed modification. Highlight changes within the text.

**Other:**

**Signature:**

**Date:**

\_\_\_\_\_  
*Principal Investigator or Sponsor Representative*

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