



<p><b>6. Does the new Principal Investigator or any co-investigator (or any member of their immediate family):</b></p> <p><b>a. Own or control an equity interest in any drug, device or technology involved in this research study?</b></p> <p><b>b. Have a financial interest in any listed source of external support (e.g., the sponsor)?</b></p> <p><b>c. Function as an advisor, employee, officer, director, or consultant for any listed commercial source of external support?</b></p> <p>If yes to any of the above is checked, please provide detailed information (on a separate sheet, if necessary) to permit the IRB to determine if such involvement should be disclosed to potential research subjects.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p><b>7a. Has the new Principal Investigator ever been charged or sanctioned by any state medical board, i.e., has a license to practice medicine ever been suspended, revoked, or restricted in any state?</b></p> <p><b>7b. Has the new Principal Investigator ever withdrawn privileges during an investigation?</b></p> <p><b>7c. Has the new Principal Investigator ever had privileges at any hospital suspended, revoked, or restricted?</b></p> <p><b>7d. Are there any criminal charges or medical board complaints pending against the new Principal Investigator?</b></p> <p><b>7e. Has the New Principal Investigator ever been suspended from research activities?</b></p> <p>If you answered yes to any of the questions above, please provide a detailed explanation.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

**8. Acknowledgement and Signature**

This Application for approval to enroll human subjects in research conducted at your site requires the assurances and signatures indicated below.

The signatures below certify that:

- The information provided in this application form is correct.
- The Principal Investigator and study personnel are aware of, and agree to conduct the research in accordance with state law, Good Clinical Practices and regulations presented in the Code of Federal Regulations (CFR) Title 21 Parts 50, 56, 312 and 812 / Title 45 Part 46 and Title 45 Parts 160-164 (the HIPAA Privacy Rule).
- The Principal Investigator (PI) will seek and obtain prior written approval from Goodwyn IRB for any substantive modification in the proposal, including, changes in procedures, co-investigators, etc.
- Unexpected or otherwise significant adverse events in the course of this study will be promptly reported to Goodwyn IRB.

- The PI or someone under the PI’s supervision will orally explain the consent form to all prospective subjects before obtaining their signature before signing
- Any significant new findings that develop during the course of this study that may affect the risks and benefits to participation will be reported in writing to Goodwyn IRB and to subjects.
- The research may not be initiated until final written approval from Goodwyn IRB is received.
- This research, once approved, is subject to continuing review and approval by Goodwyn IRB.
- The PI will comply with all Goodwyn IRB requests to report on the status of this study.
- The PI will maintain records of this research according to federal and state regulations and guidelines.
- Appropriate administrative, technical and physical safeguards to protect the privacy of protected health information are in place.

**New Principal Investigator**

***Submit the Curriculum Vitae (CV) and appropriate license(s) for the Principal Investigator.***

Your signature on this form indicates that you will be responsible for ensuring that all investigators at this site fulfill their responsibilities as Principal or Sub-Investigators as defined in the Code of Federal Regulations, the conditions listed above as well as any additional responsibilities that may be imposed by Goodwyn Institutional Review Board, Ltd. (Goodwyn IRB). If these conditions are not met, approval of this research could be suspended.

Your signature also indicates an acknowledgment and agreement that: correspondence and notifications from 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 execution of the original by the undersigned. The undersigned declare that the response and information provided in and with this form are true and correct and that no facts have been suppressed or misstated.

**Signature of New Principal Investigator**

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

Printed name of principal investigator (including middle initial and highest earned degree)

\_\_\_\_\_

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**