

Goodwyn Institutional Review Board, Ltd

Update – New Principal Investigator

Sponsor: _____ Protocol #: _____

Previous Principal Investigator: _____

New Principal Investigator: _____

Medical License Number: _____ State Issued: _____ Expiration Date: _____

You must submit the Curriculum Vitae (CV) for the new Principal Investigator (PI) with this completed form.

Contact for additional information about this report: _____

Phone: _____ Fax: _____ Email: _____

Background and History

1. Does the new Principal Investigator hold a position with another institution (university or hospital) that requires review of the investigator’s research by that institution’s IRB: Yes No
If **yes** to the above, please attach documentation of deferral/waiver of jurisdiction to Goodwyn IRB:
2. 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: Yes No
3. Has the new Principal Investigator ever withdrawn privileges during an investigation: Yes No
4. Has the new Principal Investigator ever had privileges at any hospital suspended, revoked, or restricted: Yes No
5. Are there any criminal charges or medical board complaints pending against the new Principal Investigator: Yes No
6. Has the New Principal Investigator ever been suspended from research activities: Yes No
7. If you answered yes to any of the questions above, please provide a detailed explanation: _____

New Principal Investigator Qualifications

8. Does the new Principal Investigator have less than one year of research experience: Yes No
 PI’s research experience is included in his/her CV.
 PI’s research experience is described in attached letter of explanation.
Please attach CV and/or research experience to this form.
9. Check all the training that the new principal investigator has had in the last 3 years:
 - ACRP, SOCRA, DIA Clinical Investigator/Coordinator Certifications
 - Completion of the NIH or CITI course in protection of human subjects
 - GCP Guidelines (from investigator meetings or other institution-required training)
 - Goodwyn University training in protection of human subjects
 - Review of the FDA Information Sheets and the Belmont Report
10. Has the proposed new Principal Investigator in this research study been trained in all required policies and procedures relating to Protected Health Information (HIPAA)? Yes No
If **no**, please explain: _____

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Emergency Contact

Please Note: These numbers must be incorporated into your Informed Consent Document

11. Emergency Contact: Are there any changes to the emergency phone number(s) due to the change in Principal Investigator (the number(s) that subjects are to use in case of medical questions or emergency (24 hours per day)): Yes No

If **yes**, please describe: _____

Consent Document

If you need assistance in determining the updates necessary, to your informed consent from this study, please call Goodwyn IRB at (513) 793-8900.

12. Your consent form will be updated to reflect information about the new Principal Investigator. Are there any other changes to the consent required: Yes No

If **yes**, please attach the proposed language / changes.

Conflict of Interest

Does the Principal Investigator or any Sub-Investigator with assigned responsibilities in this study (or any member of their immediate family defined as spouse or dependent child) or the research site business entity have any of the following:

NOTE: "Related to the research" means related to the sponsor, product or service being tested, or competitor of the sponsor.

13. Significant Interests (check all that apply):
- No significant interests
 - A current or recent arrangement (within the last 2 years) to serve as a speaker for the sponsor
 - Board or executive relationship related to the research regardless of compensation
 - Compensation related to the research where the amount is affected by the outcome or the total is greater than \$10K when aggregated for the immediate family.
 - Involvement in the design, conduct, or reporting of the research.
 - Ownership interest – stock options – or other financial interest related to the research where the value is affected by the outcome or is greater than \$10K when aggregated for the immediate family
 - Proprietary interest related to the research including but not limited to – a patent – trademark – copyright – or licensing agreement.

Other Changes in Personnel

If you have other changes in personnel, please complete a Personnel Update form.

14. Are there any other changes in study personnel: Yes No

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Acknowledgement and Signature

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.

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.
- 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.

Signature of Sponsor Representative

I confirm that the information submitted in this form is true and correct.

_____ Date: _____

Printed Name: _____