

Change in Principal Investigator Request Form

I. STUDY INFORMATION	
Current Principal Investigator:	
Proposed New Principal Investigator:	
Protocol Number:	
Sponsor name and/or Funding Agency:	

II. CONTACT INFORMATION		
Phone:		Fax:
Email:		
Is the new Principal Investigator's address identical to the current PI's address? <input type="checkbox"/> No* <input type="checkbox"/> Yes		
*If No, complete information below. Consent Form will also have to be updated. If address is new to study, an Additional Location Form must also be completed and submitted.		
Company:		
MAILING ADDRESS (should match Box 1 of Form FDA 1572)		
Address:		
City:	State:	Zip / Postal code:
PHYSICAL ADDRESS (if different than above)		
Address:		
City:	State:	Zip / Postal Code:

III. INVESTIGATOR INFORMATION

Attach a CV and a license for the proposed Principal Investigator and an updated Form FDA 1572.

1. Has the PI ever been disciplined by a medical/licensing board, or been convicted of a misdemeanor or felony that relates to the practice of medicine?

- Yes (*Attach a summary of the event and resolution*)
 No

2. Has the PI ever been disciplined/sanctioned by the FDA, OHRP or by an IRB? This would include issuing a reprimand, restricting the ability to conduct research or placing other conditions upon investigator.

- Yes (*Attach a summary of the event and resolution*)
 No

3. Has the PI ever been audited by the FDA, ORHP, or other regulatory agency, received a Warning Letter, a FDA 483, or other notice?

- Yes (*Attach a copy of all letters and correspondence*)
 No

4. Has the PI ever had a Sponsor or IRB impose any sanctions or restrictions on him/her, or terminate or suspend the approval of a study for any reason?

- Yes (*Attach a summary of the event and resolution*)
 No

5. Is any action or investigation currently pending from any licensing board, federal agency or courts of law concerning the professional conduct of the principal investigator in his/her capacity as a research investigator or as a clinician?

- Yes (*Attach a summary of the event and when resolution is expected*)
 No

III. INVESTIGATOR INFORMATION

6. Does the PI or immediate family of PI have a significant financial interest in this study?

Yes, one or more of the following are true: (check all that apply and provide a detailed explanation)

- Has a financial interest in the research with value that cannot be readily determined (for example, stock that is not publicly traded);
- Has a financial interest in the research with value that exceeds \$10,000 other than payments for conducting the trial as outlined in the clinical trials agreement;
- Has a financial interest in the research with value that exceeds 5% ownership;
- Has received or will receive compensation with value that may be affected by the outcome of the study;
- Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
- Has received or will receive payments other than payment for the conduct of clinical research from the sponsor that exceed \$10,000 in the last 365 days;
- Is an employee of the agency or company sponsoring the research;
- Is on the board of directors of the sponsor;
- Has a financial interest that requires disclosure to the sponsor or funding source; or
- Has any other financial interest that the investigator believes may interfere with his or her ability to protect subjects.

No, none of the above is true.

7. Indicate the human research subject protection training that the PI has completed within the past 3 years (check all that apply):

- None (site cannot be approved for research until training is completed)
- OHRP Training modules
- NIH Human Research Participant Training
- Certified Clinical Investigator (CCI) through DIA
- Completion of the Collaborative IRB Training Initiative (CITI)
- Academic/medical center's institutional human subject protection training requirements satisfied
- Clinical Research Professional (CRP) through SOCRA
- Certified Clinical Trail Investigator through ACRP
- Other (specify):

III. INVESTIGATOR INFORMATION

8. Number of studies conducted by the PI in the last year (can be approximated):

- 0 studies* 1 - 5 studies 6 - 10 studies > 10 studies

*If the PI has not conducted any studies in the last year, provide a brief description of what qualifies the PI for this study:

9. How many studies is the PI currently conducting (either as PI or sub-investigator)?

- 0 studies* 1 - 5 studies 6 - 10 studies > 10 studies*

*If the PI is currently conducting more than 10 studies, provide a brief description of the resources in place to ensure that the PI has sufficient time to conduct and complete the research:

10. Describe the reason for change in PI:

IV. NEW PRINCIPAL INVESTIGATOR AGREEMENT

As Principal Investigator I am responsible for the conduct of this research study at my site. I agree to uphold ethical standards and practices in research and conduct this study in accordance with applicable regulations. I further certify by checking each box below that:

- I will conduct this study according to the approved protocol and in accordance with ICH/GCP Guidelines, 21CFR Parts 50, 56, 312, and 812; Title 45 Part 46 and Title 45 Parts 160-164 and any additional conditions required by the FDA or Total IRB;
- My research staff and I have reviewed the Belmont Report. We understand and will uphold the three principles of research ethics set forth in the report: respect for persons, beneficence and justice;
- I will not initiate subject related activities prior to receiving the Total IRB approval letter and approved informed consent form;
- I will conduct the study in accordance with the Board-approved protocol and will not intentionally implement a change to the protocol without prior written approval from the IRB, except when necessary to eliminate an apparent immediate hazard to a subject;
- I will report changes to the protocol without prior IRB approval to eliminate an apparent immediate hazard to subjects within 24 hours of implementation;
- Either I or someone under my supervision will explain the informed consent document(s) to each prospective subject (or legally authorized representative, guardian, individual authorized to provide surrogate consent, as applicable) before obtaining his or her signature on the current, IRB approved consent document(s) and before conducting any study-related procedures;
- I have reviewed the relevant safety documents for the study product(s) (e.g., Investigator's Brochure, device manual, package insert) and am familiar with the potential risks and side effects of the study product(s);
- The research staff assisting in the conduct of this study at this site are informed of their obligations relating to the protection of human research subjects;
- The research site is adequately equipped to manage emergencies or problems that may occur during the course of this study;
- I will make myself available to discuss concerns and complaints with the subject, subject's representative, sponsor/CRO, and Total IRB during and after the conduct of the research study;
- I will notify Total IRB in writing when the study is closed at my site.

I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study at this site if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct initial and continuing reviews of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above.

Entering your name below also indicates an acknowledgment and agreement that: correspondence and notifications from Total IRB may be generated and signed in electronic form; you may print out such electronic documents in hard copy; any such printouts accurately reflect the electronic original. All such printouts shall be treated in all ways as originals. An electronic, 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.

Printed Name of Principal Investigator

Date

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V. PERSON COMPLETING FORM

By submitting this form I certify that the information contained is complete and accurate and that no facts have been suppressed or misstated. The Principal Investigator (PI) is aware of all information in this form and I am authorized to submit to the IRB on the PI's behalf.

Form Completed By

Date

Title, Company

Phone:

Email: