

**CHANGE OF PRINCIPAL INVESTIGATOR FORM**

*\*We accept study submissions by email, fax or mail.*

<b>1. STUDY INFORMATION</b>	
<b>A. Sponsor:</b>	<b>Protocol No.:</b>
<b>B. Study Title:</b>	
<b>2. EXITING (previous) Principal Investigator (PI) Name:</b>	
<b>3. NEW INVESTIGATOR INFORMATION</b>	
<b>A. New Principal Investigator (PI) Name:</b>	Attach NEW PI's CV, License(s)
<b>PI Phone:</b>	
<b>PI Fax:</b>	
<b>PI E-mail:</b>	
<i>If the site address/name and/or subject phone numbers is/are also changing, please also complete the 'Site Information Change Submission Form'</i>	
<p><i>Alpha IRB will revise the site's consent form(s) and provide new IRB approved version(s) with the new Principal Investigator's information.</i></p> <p><i>If additional changes to the informed consent form(s) are needed, please submit a tracked changes copy of your current informed consent form(s) in Word format for review. You can request a copy of the site's Word format informed consent form(s) by contacting Alpha IRB.</i></p>	
<b>B. Does the PI, the PI's immediate family, study staff or the study staff's immediate family have a financial interest (other than payment) in this study that has not been previously reported to Alpha IRB?</b>	Interests that require disclosure are described in the Alpha IRB Financial Disclosure Form and in the IRB Guidebook
<input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, please complete a 'Financial Disclosure Form' for each individual with a financial interest)	
<b>Does the PI, the PI's immediate family, study staff or the study staff's immediate family have an interest, other than financial, in the outcome of this study that has not been previously reported to Alpha IRB?</b>	Interests that require disclosure are described in the Alpha IRB Financial Disclosure Form and in the IRB Guidebook
<input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, please complete a 'Financial Disclosure Form' for each individual with a financial interest)	

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<p><b>C.</b></p>	<p><b>Please indicate the human research participant protection training the Principal Investigator has completed within the past 3 years (Check all that apply):</b></p> <p><input type="checkbox"/> Review of the following: GCP Guidelines, relevant FDA Information Sheets, and the Belmont Report (links below)  <a href="https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notice/guidance-documents">https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notice/guidance-documents</a>  <a href="http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm">http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm</a>  <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html">http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html</a></p> <p><input type="checkbox"/> DIA, ACRP, or SOCRA Training and/or Certification</p> <p><input type="checkbox"/> CITI Program Courses (<i>Available through Alpha IRB</i>) - <a href="https://www.citiprogram.org/">https://www.citiprogram.org/</a></p> <p><input type="checkbox"/> OHRP Online Assurance Training Course - <a href="https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training">https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training</a></p> <p><input type="checkbox"/> Completion of self-study or other training specific to human research participant protection</p> <p>OR</p> <p><input type="checkbox"/> None</p>
<p><b>D.</b></p>	<p><b>If you checked self-study or other training specific to human research participant protection, please check all that apply:</b></p> <p><input type="checkbox"/> Investigator Meetings</p> <p><input type="checkbox"/> Clinic/CRO/SMO Training (please describe):</p> <p><input type="checkbox"/> Web Based HRPP Training (please describe):</p> <p><input type="checkbox"/> Other (please describe):</p>
<p><b>E.</b></p>	<p><b>If the Principal Investigator has not completed any training on human research participant protection, what method of training will be completed? (Check all that apply):</b>  <i>(Note: acceptable forms of training, such as those listed below, must be complete before full IRB approval is granted)</i></p> <p><input type="checkbox"/> Investigator Meetings</p> <p><input type="checkbox"/> Clinic/CRO/SMO Training (please describe):</p> <p><input type="checkbox"/> Web Based HRPP Training (please describe):</p> <p><input type="checkbox"/> Other (please describe):</p>
<p><b>F.</b></p>	<p><b>Has the Principal Investigator confirmed that the research staff and key personnel at this facility have been appropriately trained, are aware of their obligations with regard to human research participant protection regulations and can perform their assigned duties?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, please describe how this will be addressed:</b></p>

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<p><b>G.</b></p>	<p><b>Do any of the below apply to the PI involved with this study?</b></p> <p>Been audited (inspected) by any regulatory agency (FDA, OHRP, etc.) in the last five (5) years?  <input type="checkbox"/> No <input type="checkbox"/> Yes – attach documentation</p> <p>Been convicted of a crime, received an FDA Warning Letter, received Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE), received a suspension by a federal or governmental agency (such as FDA, HHS, and/or an OHRP Determination Letter <u>at any time in the past</u>)?  <input type="checkbox"/> No <input type="checkbox"/> Yes – attach documentation</p> <p>Been sanctioned by any IRB or had an IRB suspend or terminate a study for any reason?  <input type="checkbox"/> No <input type="checkbox"/> Yes – attach documentation</p> <p>Been disciplined/reprimanded by a public or private medical organization, disciplined/reprimanded by a licensing authority, or had any other legal or regulatory actions /restrictions (entered into either voluntarily or involuntarily) related to the practice of medicine or research <u>at any time in the past</u>?  <input type="checkbox"/> No <input type="checkbox"/> Yes – attach documentation</p>	<p>Attach documents for all 'yes' answers. (e.g. 483 &amp; site response, FDA warning letter, letters from medical board, etc.)</p>
<p><b>H.</b></p>	<p><b>How long has the PI been conducting human subjects research?</b></p> <p>Years                  Months</p>	
<p><b>I.</b></p>	<p><b>How many studies / clinical trials has the PI conducted in the past (as either a PI or Sub-I)?</b></p>	
<p><b>J.</b></p>	<p><b>Is the PI's human subjects research experience listed on his/her CV (Including specific study information and dates)?</b></p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No – If no, describe the specific studies the PI has been involved in (include dates):  <input type="checkbox"/> N/A – no prior human subjects research experience</p>	<p>Include specific study info and dates. Attach additional pages, if needed</p>
<p><b>K.</b></p>	<p><b>How many studies is the PI currently involved in as a PI?</b></p> <p><b>How many studies is the PI currently involved in as a Sub-Investigator?</b></p>	
<p><b>L.</b></p>	<p><b>Number of clinical research staff the PI will supervise on this project:</b></p> <p><b>Sub-I's:</b>  <b>Research Coordinators:</b>  <b>Other staff (nurses, technicians, etc.):</b></p>	
<p><b>4. INFORMATION CHANGES</b></p>		
<p><b>A.</b></p>	<p><b>Are there any changes that you are aware of to state/ local laws that might impact or influence the conduct of the study from what was reported on the previous PI's submission form?</b></p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:</p>	<p>Attach copies of any relevant state laws, if applicable</p>
<p><b>B.</b></p>	<p><b>Are there any changes to community attitudes that may adversely affect subjects in this study from what was reported on the previous PI's submission form?</b></p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:</p>	<p>Describe on separate page if needed</p>

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C.	<p><b>Will the compensation to study subjects change from what was reported on the previous PI's submission form?</b>  <input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:</p>	Describe on separate page if needed
D.	<p><b>Are there any changes regarding the enrollment of vulnerable populations from what was reported on the previous PI's submission form?</b>  <input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:</p>	Describe on separate page if needed
E.	<p><b>Are there any changes to your process of obtaining informed consent from what was reported on the previous PI's submission form?</b>  <input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:</p>	Describe on separate page if needed
F.	<p><b>Are there any other changes from what was reported on the previous PI's submission form as a result of this Principal Investigator change?</b>  <input type="checkbox"/> No <input type="checkbox"/> Yes – please describe:</p>	Describe on separate page if needed

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**By signing this form, I am confirming that I am the Principal Investigator (PI) or the PI's designee authorized to submit on behalf of the PI and that the PI is aware of the information contained in this submission. The PI acknowledges they are responsible for understanding and complying with all local context issues, policies, and procedures, including the conduct of my sub-investigator(s) and staff and the requirements and/or conditions of Alpha IRB. The PI agrees to all of the following:**

- 1) I have read, understand and will follow the approved protocol in accordance with ICH Guidelines for Good Clinical Practice, the applicable Federal regulations, state laws, local regulations governing clinical research and any additional IRB requirements, including the policies set forth in the current Alpha IRB Investigator Guidebook (available online at [www.alpha-irb.com](http://www.alpha-irb.com)).
- 2) I will not initiate this research study until I have received approval documentation from Alpha IRB.
- 3) I will obtain written approval to modify the study protocol or informed consent before implementing any changes to the protocol or informed consent except when an immediate change is necessary to eliminate an apparent and immediate hazard to human subjects and I agree to report to the IRB within 5 working days any change to research that is necessary for subject safety that was implemented without IRB approval.
- 4) I, or my designee, will obtain an IRB approved informed consent for each potential subject (or legally authorized representative, guardian, individual authorized to provide surrogate consent, as applicable) *unless waived by the IRB* allowing adequate time in a private environment to read and review and consider their participation in this study. Prospective subjects will have the informed consent explained orally and be given the opportunity to ask question and have them answered and to be able to take the consent document home to consider with family / friends / personal physician.
- 5) I or my designee will carefully explain the treatment and compensation of research related injuries.
- 6) I attest that my contracts with the sponsor obligates the sponsor to promptly report to Alpha Independent Review Board, Inc. any findings of study monitors, or any study results, obtained as part of the study or after the study has closed, that could affect the safety of participants, affect the willingness of participants to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.
- 7) I will notify the IRB within *10 business days* from the date of discovery any significant deviation from the protocol that adversely affects the safety, rights or welfare of subjects or others, or the integrity of the study data, any possible unanticipated problems involving risk to participants or others; including reportable serious, unexpected and related adverse events, breaches of confidentiality, complaints from subjects when the complaints indicate unexpected risks or cannot be resolved by the research team, information that indicated a change to the risks or potential benefits of the research, urgent data and safety monitoring reports from the sponsor, findings or allegations of non-compliance, changes in FDA labeling or withdrawal from the marketing of a drug, device or biologic used in a research protocol, incarceration of a subject in a protocol overseen by Alpha IRB, events that requires reporting to sponsor, sponsor-imposed suspensions for risk, in addition to FDA 483's, warning letters and or other audit correspondence and my written response to the finding and corrective action (if applicable), any other audit report by a regulator agency and/or sponsor or IRB and any other problem that I consider to be unanticipated, related or possibly related to the study and indicates that subjects or others are at increased risk of harm.
- 8) I attest that my contract with the sponsor obligates the sponsor to communication of results from a research study to participants when those results directly affected their safety or medical care
- 9) I will obtain IRB approval of all recruitment materials prior to their use.
- 10) I will submit Research Continuing Review Forms and Site Continuing Review Forms by their due date and will respond to all requests from Alpha IRB in a timely manner.
- 11) I agree to notify Alpha IRB in writing when the study has closed.
- 12) I agree to allow Alpha IRB to check the validity of my license and the information on my resume and to perform site visits. This form will not be considered confidential and it may be viewed by regulatory bodies, accrediting bodies and others with a legal right.
- 13) I will protect the rights, safety and welfare of each participant to the best of my ability and will put their personal rights and welfare first.

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I certify that I am the PI or the PI's designee authorized to submit on behalf of the PI, that the PI has full awareness of the information within this form and the information provided in this form is true and correct.

Printed Name Principal Investigator (or Designee): \_\_\_\_\_

Title (for Designee): \_\_\_\_\_

Signature Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

**SITE CHECKLIST**

Please ensure the following items are included in your submission package (as applicable):

- Principal Investigator's current CV (signed/dated within last 2 years)
- Principal Investigator's License(s)

**ONLY SUBMIT THE FOLLOWING IF YOU HAVE SITE SPECIFIC CHANGES TO THE IRB APPROVED SPONSOR TEMPLATE(S)**

- Informed Consent Form(s) (in Word Format with your site's **changes tracked**):  Main  Genetic  Assent
- Sub-study  Other