

SITE SUBMISSION FORM (MULTI-CENTER)

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

1. STUDY INFORMATION			
A.	Sponsor:	Protocol No.:	
B.	Study Title:		
C.	<p>Is this study Federally funded? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, what is your Federal-wide Assurance (FWA) number? :</p> <p>What federal agency is providing the funds? :</p> <p>Please explain if your FWA number is unavailable:</p>		
2. INVESTIGATOR & SITE INFORMATION			
A.	Principal Investigator (PI):		
	Primary Site Name:	Phone:	Attach PI's CV, License(s)
	Primary Site Address:	Fax:	
		E-mail:	
B.	Who will be the main contact for this study?		
	Name:	Phone:	
	Position/Title:	Email:	
C.	What are the phone numbers for subject use? – To be included in the consent form		
	Phone:	24 Hour Phone:	
D.	<p>Will the PI be conducting study related activity at other locations?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes – if yes, please indicate the number of additional locations:</p> <p>If yes, complete an 'Additional Study Location Form' for <u>each</u> location.</p>		
E.	<p>Is this site under the jurisdiction of a local IRB (i.e. the site requires that IRB oversight of this study be waived or authorized to Alpha IRB)?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes - if yes, you may provide a copy of your reliance / authorization agreement to Alpha IRB, or you may request a copy of Alpha IRB's Jurisdictional Waiver, if needed.</p>		

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<p>F.</p>	<p>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?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, please complete a 'Financial Disclosure Form' for each individual with a financial interest)</p> <p>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?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, please complete a 'Financial Disclosure Form' for each individual with a financial interest)</p>	<p>Interests that require disclosure are described in the Alpha IRB Financial Disclosure Form and in the IRB Guidebook</p>
<p>G.</p>	<p>Has this study ever been submitted to another IRB for review? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>If yes, list the name of the IRB(s) and the outcome of the review:</p>	
<p>H.</p>	<p>Please indicate the human research participant protection training the Principal Investigator has completed within the past 3 years (Check all that apply):</p> <p><input type="checkbox"/> Review of the following: GCP Guidelines, relevant FDA Information Sheets, and the Belmont Report (links below) https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notices/ich-guidance-documents http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html</p> <p><input type="checkbox"/> DIA, ACRP, or SOCR Training and/or Certification</p> <p><input type="checkbox"/> CITI Program Courses (Available through Alpha IRB) - https://www.citiprogram.org/</p> <p><input type="checkbox"/> OHRP Online Assurance Training Course - https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training</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>I.</p>	<p>If you checked self-study or other training specific to human research participant protection, please check all that apply:</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>J.</p>	<p>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):</p> <p><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>	

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<p>K.</p>	<p>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? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, please describe how this will be addressed:</p>	
<p>L.</p>	<p>Do any of the below apply to the PI involved with this study?</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 & site response, FDA warning letter, letters from medical board, etc.)</p>
<p>M.</p>	<p>How long has the PI been conducting human subjects research?</p> <p>Years or Months</p>	
<p>N.</p>	<p>How many studies / clinical trials has the PI conducted in the past (as either a PI or Sub-I)?</p>	
<p>O.</p>	<p>Is the PI's human subjects research experience listed on his/her CV (Including specific study information and dates)?</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>P.</p>	<p>How many studies is the PI currently involved in as a PI?</p> <p>How many studies is the PI currently involved in as a Sub-Investigator?</p>	
<p>Q.</p>	<p>Number of clinical research staff the PI will supervise on this project:</p> <p>Sub-I's: Research Coordinators: Other staff (nurses, technicians, etc.):</p>	
<p>R.</p>	<p>Does the site have adequate resources, including staff and medical or psychosocial resources, to conduct this study? <input type="checkbox"/> Yes <input type="checkbox"/> No - if no, explain:</p>	

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S.	Methods to control the study article(s): Do you agree to following measures if the study involves study product (including investigational products, placebo, approved drugs or devices, or approved comparators)? <ul style="list-style-type: none"> • All study product(s) will be stored in a secure area; and • Access to the study product(s) will be limited to authorized research personnel. <input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain: <input type="checkbox"/> N/A – this study does not involve study product											
T.	What resources are available at this site to treat emergencies, if they occur? <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> BLS certified personnel</td> <td><input type="checkbox"/> Emergency medication</td> </tr> <tr> <td><input type="checkbox"/> ACLS certified personnel</td> <td><input type="checkbox"/> Crash cart</td> </tr> <tr> <td><input type="checkbox"/> Emergency response team within facility</td> <td><input type="checkbox"/> Access to 911</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other (please describe):</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> N/A - emergency procedures are not applicable to this research. Please explain why:</td> </tr> </table>	<input type="checkbox"/> BLS certified personnel	<input type="checkbox"/> Emergency medication	<input type="checkbox"/> ACLS certified personnel	<input type="checkbox"/> Crash cart	<input type="checkbox"/> Emergency response team within facility	<input type="checkbox"/> Access to 911	<input type="checkbox"/> Other (please describe):		<input type="checkbox"/> N/A - emergency procedures are not applicable to this research. Please explain why:		
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U.	Name of the nearest emergency facility to be used in the event of an emergency: Distance to emergency facility from this study site: miles											

3.	SUBJECT INFORMATION																										
A.	What is the diversity of the population from which you plan to recruit? <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">Ethnicity: (must total 100%)</td> <td style="width: 33%;">Race: (must total 100%)</td> <td style="width: 34%;"></td> </tr> <tr> <td><table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>Hispanic or Latino: %</td></tr><tr><td>Not Hispanic or Latino: %</td></tr></table></td> <td><table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>White: %</td><td>Black or African American: %</td><td>Native Hawaiian or Other Pacific Islander: %</td></tr><tr><td>Asian: %</td><td>American Indian or Alaska Native: %</td><td>Other: %</td></tr></table></td> <td></td> </tr> <tr> <td>Gender: (must total 100%)</td> <td>Age: (must total 100%)</td> <td></td> </tr> <tr> <td><table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>Male: %</td></tr><tr><td>Female: %</td></tr></table></td> <td><table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>0 – 17: %</td></tr><tr><td>18 – 64: %</td></tr><tr><td>65 – >: %</td></tr></table></td> <td></td> </tr> </table>	Ethnicity: (must total 100%)	Race: (must total 100%)		<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>Hispanic or Latino: %</td></tr><tr><td>Not Hispanic or Latino: %</td></tr></table>	Hispanic or Latino: %	Not Hispanic or Latino: %	<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>White: %</td><td>Black or African American: %</td><td>Native Hawaiian or Other Pacific Islander: %</td></tr><tr><td>Asian: %</td><td>American Indian or Alaska Native: %</td><td>Other: %</td></tr></table>	White: %	Black or African American: %	Native Hawaiian or Other Pacific Islander: %	Asian: %	American Indian or Alaska Native: %	Other: %		Gender: (must total 100%)	Age: (must total 100%)		<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>Male: %</td></tr><tr><td>Female: %</td></tr></table>	Male: %	Female: %	<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td>0 – 17: %</td></tr><tr><td>18 – 64: %</td></tr><tr><td>65 – >: %</td></tr></table>	0 – 17: %	18 – 64: %	65 – >: %		
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B.	Are there any state or local laws that you are aware of that might impact or influence the conduct of the study? <input type="checkbox"/> No <input type="checkbox"/> Yes – check all that apply below: <input type="checkbox"/> State laws related to the use of Protected Health Information/HIPAA - please explain: <input type="checkbox"/> California Experimental Subject's Bill of Rights <input type="checkbox"/> Age of majority different than 18 - please explain: <input type="checkbox"/> Other - please explain:	Attach copies of any relevant state laws, if applicable																									

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<p>C.</p>	<p>Are there any community attitudes that may adversely affect subjects in this study?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>If yes, describe attitudes and how they may affect subjects:</p>	<p>Describe on separate page if needed</p>
<p>4. VULNERABLE POPULATIONS</p>		
<p>A.</p>	<p>Do you intend to enroll any vulnerable populations?</p> <p><input type="checkbox"/> Yes – please select all that apply below <input type="checkbox"/> No – proceed to section 5.</p> <p><i>(please include populations that are included in the protocol as well as those that may be enrolled based on your site’s demographics)</i></p> <p>Enrollment of a vulnerable population is not allowed unless first approved by the IRB</p>	<p>Attach additional information if needed.</p>
<p>B.</p>	<p><input type="checkbox"/> Children/minors (note: 19 is the age of majority in Alabama and Nebraska; 21 is the age of majority in Puerto Rico.)</p> <ul style="list-style-type: none"> • What is the age range of the minor subject you will be enrolling?: • Will children or minors without parent be enrolled? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide justification in terms of state law or a decision by legal counsel of who can act as a guardian for research purposes in your state: • What is the legal age of consent to intervention or procedures associated with the research under state or local law? _____ years of age • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ Parental/guardian permission will be obtained as required by the IRB ○ Children over the age of 7 must agree to participate in the research and provide written assent using the IRB approved assent form ○ The assent form will be written at an age appropriate level ○ The site will ensure the subject and the subject’s parent(s)/guardian will not be unduly influenced to participate <p><input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:</p>	<p>Please provide copy of Assent Form</p>

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<p>C.</p>	<p><input type="checkbox"/> Non-English speaking</p> <ul style="list-style-type: none"> • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ The consent form and applicable study related materials will be translated into a language understandable to the subject ○ A member of the research team/non-family member interpreter will be available to interpret the initial and ongoing informed consent discussion for the subject ○ In case of emergencies, a member of the research team who is fluent in the subject's language will be available OR the research team has 24-hour access to a translation service that can sufficiently communicate to the subject <p><input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:</p> <ul style="list-style-type: none"> • Into what language(s) will the ICF/study materials need to be translated?: • Would you like Alpha IRB to facilitate the translation of the Consent Form(s) and/or Study materials? <ul style="list-style-type: none"> <input type="checkbox"/> Yes – please indicate which materials will need translation: <input type="checkbox"/> No – the site will facilitate translation and provide copies of the translated materials, along with copies of certifications, to Alpha for approval. 	<p>All translated materials must be submitted to Alpha IRB for approval prior to use.</p> <p>All translated materials must be accompanied by a certification of accuracy.</p>
<p>D.</p>	<p><input type="checkbox"/> Economically disadvantaged</p> <ul style="list-style-type: none"> • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ Compensation will be set at a meaningful, prorated level that compensates the participant for her/his time ○ Compensation will be not so great that it unduly influences a participant's decision to enroll. <p><input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:</p>	
<p>E.</p>	<p><input type="checkbox"/> Employees of site, family members of site staff</p> <ul style="list-style-type: none"> • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ The investigator will make known to employee(s) or family member that their participation in this study is strictly voluntary and their decision to participate, or not to participate, will have no impact on the performance evaluations, job advancement, or employment status of the employee ○ No action will be taken against an employee based on information that the investigator would not otherwise be entitled but obtains due to the employee's/family member's participation in the study ○ Measures will be taken to ensure the confidentiality of an employee's study-related records ○ Confirm that the protocol inclusion/exclusion criteria does not prohibit the enrollment of site employees/family members of employees into the study <p><input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:</p> <p><i>Note - an additional statement will be added to the site's informed consent form(s) (if not already included) regarding the enrollment of employees of site and family members of site staff.</i></p>	

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F.	<input type="checkbox"/> Illiterate/unable to read (including those with visual impairment) <ul style="list-style-type: none"> • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ An impartial witness (not affiliated with the research) will be present during the entire consent process to attest to the accuracy of the presentation, the apparent understanding of the subject and that consent was freely given by the subject ○ The impartial witness will sign and date the consent form <input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain: <i>Note - an impartial witness signature line will be added to the site's informed consent form(s) (if not already included)</i>	
G.	<input type="checkbox"/> Pregnant Women <ul style="list-style-type: none"> • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ Individuals engaged in the research will have no part in: <ul style="list-style-type: none"> ▪ 1) any decisions as to the timing, method, or procedures used to terminate a pregnancy, and ▪ 2) determining the viability of the fetus at the termination of the pregnancy; and ○ No inducements, monetary or otherwise, will be offered to terminate the pregnancy ○ I will obtain the consent of the father, if required <input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:	
H.	<input type="checkbox"/> Terminally ill patients <ul style="list-style-type: none"> • Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> ○ The potential risks and benefits and the likelihood of the risks and any personal benefits associated with participation will be clearly explained to the subject in a manner that will neither create false hope nor eliminate all hope ○ The investigator will make known to the subject(s) other possible alternative options including standard of care and other investigational procedures he/she may wish to explore ○ It will be emphasized to subjects that there are no adverse consequences if they choose not to participate in the study <input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:	

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<p>H.</p>	<p><input type="checkbox"/> Adults with diminished decision-making capacity / cognitively impaired subjects <i>(Please note: the protocol must address the inclusion of these subjects. If the approved protocol does not specifically allow for enrollment of adults with diminished decision-making capacity / cognitively impaired subjects, you may not include these subjects in the study.)</i></p> <ul style="list-style-type: none"> Do you agree to adhere to the following additional protections? <ul style="list-style-type: none"> <input type="checkbox"/> The subject will be assessed and the PI will determine whether they are competent to provide consent on their own behalf. <input type="checkbox"/> The subject will not be enrolled or continue in the study unless they provide ongoing, affirmative assent. <input type="checkbox"/> The site will ensure that the subject is not being unduly influenced to participate or to continue participation <input type="checkbox"/> The site will ensure a legally authorized representative (LAR) is used when appropriate, allowed by the protocol, and approved by Alpha IRB. <i>Note: If use of an LAR is approved, Alpha IRB will add additional LAR signature blocks to the consent form.</i> <p><input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:</p> <ul style="list-style-type: none"> Please provide a description of how capacity for consent or assent will be determined: Will subjects with legally authorized representatives* (LARs) be enrolled? <input type="checkbox"/> Yes <input type="checkbox"/> No - If no, please explain: If yes, is use of an LAR acceptable per the protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No - explain: If yes, provide justification in terms of state law or a decision by legal counsel of who constitutes an LAR in your state: <p><small>*A legally authorized representative is defined as an individual, or juridical or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.</small></p>	<p>The site/PI is responsible for knowing who can serve as a LAR in your state.</p> <p>Or submit on separate page</p>
<p>I.</p>	<p><input type="checkbox"/> Other Vulnerable Population(s) not listed above</p> <ul style="list-style-type: none"> Describe the population(s) and the additional protections that will be taken: 	<p>Or submit on separate page</p>

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5. INFORMED CONSENT		
A.	Who will conduct the informed consent process with the potential subjects? <input type="checkbox"/> PI <input type="checkbox"/> Sub-I <input type="checkbox"/> Research Coordinator <input type="checkbox"/> Other:	Check all that apply
B.	Will your process to obtain informed consent adhere to the following standards? <ul style="list-style-type: none"> • Informed consent will be obtained prior to performing any study related procedures. • Only the most current IRB approved Informed Consent Form(s) will be used when obtaining written informed consent. • The person conducting the consent process will spend as much time as needed to thoroughly explain and answer any questions the potential subject may have about the study. • The PI, Sub-I, or other medically qualified staff will also be available to answer any questions the potential subject may have about the study, as necessary. • The potential subject will be allowed as much time as is necessary to consider their decision to enroll in the study, including taking the consent form home for further consideration prior to signing it, if requested. • Informed consent must be presented in a language understandable to the subject. • The consent process will not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of their legal rights, or releases or appears to release the investigator, the sponsor, the institution/site, or its agents from liability for negligence. • To minimize the possibility of coercion or undue influence, it will be emphasized to the subject that there are no adverse consequences if they choose not to participate in the study and equal emphasis will be put on all elements of consent (i.e. risks vs. benefits). • The research team will evaluate whether the potential subject understands the information provided during the consent process, and will not enroll a potential subject who does not understand. • If the subject agrees to participate, the consent form(s) will be signed and dated by the subject and the research staff member who is obtaining consent. • The subject will be given a copy of their signed and dated consent form(s) to take home. <input type="checkbox"/> Yes <input type="checkbox"/> No – if no, please explain:	
C.	Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the Sponsor contract? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A - If no or N/A, please explain:	
6. SUBJECT RECRUITMENT AND ADVERTISING		
A.	What methods will you use to recruit subjects for this study? (select all that apply)	
	<input type="checkbox"/> Direct advertising (ads, flyers, etc.) <input type="checkbox"/> Investigator's patients <input type="checkbox"/> Physician referrals	
	<input type="checkbox"/> Database of potential subjects <input type="checkbox"/> Phone screening <input type="checkbox"/> None	
	<input type="checkbox"/> Other:	
B.	If you checked 'Database of potential subjects', have these individuals given <u>prior permission</u> to be contacted? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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C.	<p>Are you submitting any recruitment and/or study materials at this time? (this does not include study-wide template materials already submitted by the sponsor and approved by the IRB)</p> <p><input type="checkbox"/> No – Proceed to section 7.</p> <p><input type="checkbox"/> Yes – the following materials are being submitted with this submission (select all that apply)</p>	All subject materials must be approved by Alpha IRB prior to use																																				
	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%;"><input type="checkbox"/> Radio/TV Ad</td> <td style="width:33%;"><input type="checkbox"/> Phone Screen</td> <td style="width:33%;"><input type="checkbox"/> Website/Internet Ad</td> </tr> <tr> <td><input type="checkbox"/> Newspaper/Print Ad</td> <td><input type="checkbox"/> Bulletin Board/Flyer</td> <td><input type="checkbox"/> Letter/PSA</td> </tr> <tr> <td><input type="checkbox"/> Brochure/Handout</td> <td><input type="checkbox"/> Subject Diary</td> <td><input type="checkbox"/> Reminder Card</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Other:</td> </tr> </table>	<input type="checkbox"/> Radio/TV Ad	<input type="checkbox"/> Phone Screen	<input type="checkbox"/> Website/Internet Ad	<input type="checkbox"/> Newspaper/Print Ad	<input type="checkbox"/> Bulletin Board/Flyer	<input type="checkbox"/> Letter/PSA	<input type="checkbox"/> Brochure/Handout	<input type="checkbox"/> Subject Diary	<input type="checkbox"/> Reminder Card	<input type="checkbox"/> Other:																											
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<input type="checkbox"/> Other:																																						
D.	<p>Will you require a partial waiver of authorization for screening or recruitment purposes?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes - complete a 'Request for Partial Waiver of Authorization Form'</p> <p><i>Please note: use or disclosure of an individual's protected health information (PHI) by a covered entity for screening and recruitment purposes requires the individual's written authorization, unless a waiver or partial waiver of authorization is granted by the IRB; in which case authorization may be given orally by the individual. If you are a covered entity utilizing a phone screen, you may be required to submit a partial waiver request in order to use/disclose PHI.</i></p>																																					
7.	PAYMENT TO SUBJECTS																																					
A.	<p>Are subjects being compensated for their participation?</p> <p><input type="checkbox"/> Yes - complete sections B – E below <input type="checkbox"/> No – proceed to section 8.</p>																																					
B.	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4" style="text-align:center;">Subjects will be compensated as indicated below:</th> </tr> <tr> <th style="width:25%;">Visit Number / Type (e.g. Screening, Visit 4, Visits 1-3,etc.)</th> <th style="width:25%;">Amount</th> <th style="width:25%;">Visit Number / Type (continued)</th> <th style="width:25%;">Amount (continued)</th> </tr> </thead> <tbody> <tr> <td></td> <td style="text-align:center;">\$</td> <td></td> <td style="text-align:center;">\$</td> </tr> <tr> <td></td> <td style="text-align:center;">\$</td> <td></td> <td style="text-align:center;">\$</td> </tr> <tr> <td></td> <td style="text-align:center;">\$</td> <td></td> <td style="text-align:center;">\$</td> </tr> <tr> <td></td> <td style="text-align:center;">\$</td> <td></td> <td style="text-align:center;">\$</td> </tr> <tr> <td></td> <td style="text-align:center;">\$</td> <td></td> <td style="text-align:center;">\$</td> </tr> <tr> <td></td> <td style="text-align:center;">\$</td> <td></td> <td style="text-align:center;">\$</td> </tr> <tr> <td colspan="4">Total potential compensation for study visits: \$</td> </tr> </tbody> </table>	Subjects will be compensated as indicated below:				Visit Number / Type (e.g. Screening, Visit 4, Visits 1-3,etc.)	Amount	Visit Number / Type (continued)	Amount (continued)		\$		\$		\$		\$		\$		\$		\$		\$		\$		\$		\$		\$	Total potential compensation for study visits: \$				You may list more than one visit number per line. Attach additional pages if needed.
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C.	<p>Form of Payment:</p> <p><input type="checkbox"/> Check <input type="checkbox"/> Cash <input type="checkbox"/> Gift Certificate/Card – list type (e.g. Visa): <input type="checkbox"/> Other:</p>																																					
D.	<p>Will a 1099 be issued?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes - If yes, select all that apply to protect confidentiality</p> <p><input type="checkbox"/> Mail to subjects address provided to our site</p> <p><input type="checkbox"/> Subject may receive from site with proper ID</p>																																					

SITE SUBMISSION FORM (MULTI-CENTER)

E.	When will subject receive his/her compensation? <input type="checkbox"/> At each completed study visit <input type="checkbox"/> At the subjects final study visit <input type="checkbox"/> Within <indicate #> weeks of subjects final study visit <input type="checkbox"/> Other – please describe:	Attach additional pages if needed.
8. PRIVACY INFORMATION		
<i>“Privacy Interests” – refers to the interest of individuals in being left alone, limiting access to themselves and limiting access to their information.</i>		
A.	Will personal information collected from subjects be limited to only that which is necessary for the study purpose? *If no, please provide an explanation:	<input type="checkbox"/> Yes <input type="checkbox"/> No*
B.	Will subjects’ personal information be collected in a private setting/location away from the public (when applicable)? *If no, please provide an explanation:	<input type="checkbox"/> Yes <input type="checkbox"/> No*
C.	Will the study-related assessments and procedures be conducted in a private setting/location? *If no, please provide an explanation:	<input type="checkbox"/> Yes <input type="checkbox"/> No*
D.	Is there any additional provision at your site to protect the privacy of subjects? *If yes, please describe:	<input type="checkbox"/> Yes* <input type="checkbox"/> No

SITE SUBMISSION FORM (MULTI-CENTER)

9.	CONFIDENTIALITY OF SUBJECT INFORMATION		
	<i>Medical records and research records are different. They are handled differently and are subject to different protection. (this question relates to research data)</i>		
A.	Will paper based records be kept in a secure location and only accessible to personnel involved with the study? *If no, please provide an explanation:	<input type="checkbox"/> Yes <input type="checkbox"/> No*	
B.	Will computer based files be password protected and only be made available to personnel involved with the study? *If no, please provide an explanation:	<input type="checkbox"/> Yes <input type="checkbox"/> No*	
C.	Will identifiers be removed from study related information whenever feasible and as soon as possible? *If no, please provide an explanation:	<input type="checkbox"/> Yes <input type="checkbox"/> No*	
D.	Are there any additional provisions at your site to protect the confidentiality of subject information? (e.g. study personnel will be required to sign statements agreeing to protect the security/ confidentiality of study information prior to being granted access) *If yes, please describe:	<input type="checkbox"/> Yes* <input type="checkbox"/> No	
E.	Will personnel not directly related to the research have access to study records or data? <input type="checkbox"/> No <input type="checkbox"/> Yes - If yes, check all that apply below: <input type="checkbox"/> Billing Office <input type="checkbox"/> Medical Records <input type="checkbox"/> Hospital Personnel <input type="checkbox"/> Other:		

SITE SUBMISSION FORM (MULTI-CENTER)

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).
- 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.

SITE SUBMISSION FORM (MULTI-CENTER)

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 (or Designee): _____ **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)
- Site specific Study/Recruitment Material(s): Ads Screening Forms Diary Questionnaires Scales
 Other
- Additional Study Location Form(s)
- Financial Disclosure Form(s)
- Request for Partial Waiver of Authorization Form
- 1572 (optional)

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