Alpha IRB
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
T: 949-542-3882 F: 949-940-0134

Full Accreditation

www.alphairb.com

SITE SUBMISSION FORM (SINGLE SITE)

We accept study submissions by email, fax or mail.

1. STUDY INFORMATION

A. **Sponsor:** **Protocol No.:**

Study Title:

B. **Study Type:** ☐ Drug, Biologic or Dietary Supplement *(please complete section C., then proceed to section E.)*
☐ Device *(please complete section D., then proceed to section E.)*
☐ Social/Behavioral *(please proceed to section E.)*
☐ Other (blood draw, evaluation, diagnostic test, etc.): *(please proceed to section E.)*

C. **Drug, Biologic or Dietary Supplement Study Information:**

I. **Phase:** ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Other:

II. **Is this study being conducted under an IND?** ☐ Yes ☐ No

a. **If yes,** what is the IND number for this study? IND#:

Please support your IND # by identifying which of following applies:

☐ The sponsor protocol has the IND # listed on it
☐ I am providing a letter from the sponsor indicating the IND # - please attach
☐ I am providing a letter from the FDA - please attach
☐ Other (e.g. correspondence from sponsor which references IND #) - please attach

Please indicate the status of your IND by identifying which of following applies:

☐ The IND is active and the study can begin once IRB approval is obtained
☐ The IND application was sent to and received by the FDA, but is not in effect

Please note: the study may not commence until the IND is in effect

☐ Other – please explain:

b. **If no,** please identify which of the following applies:

☐ The investigation meets the criteria at § 21 CFR 312.2(b), or a BA/BE study that does not meet criteria at § 21 CFR 320.31. Attach an explanation citing the criteria or a letter from the FDA indicating why study is exempt from an IND.

☐ The study is evaluating botanical dietary supplement(s) for dietary supplement use (i.e., structure and/or function claims only) and not for its effect on disease(s). Attach an explanation or letter from the FDA indicating why study does not require an IND. *Note: you will be required to seek an IND if your protocol is designed to provide info on a health claim, unless a letter from FDA is provided.*

☐ Other - Attach an explanation or letter from the FDA indicating why study does not require an IND.

III. **Does this study involve a radioactive drug?** ☐ Yes ☐ No

If yes, please provide a copy of the approval by a Radioactive Drug Research Committee.

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Please provide a copy of the Investigator's Drug Brochure(s) (IND Studies) and/or package insert / label / product information (FDA approved drugs)

D. Device Study Information:

I. **Is the device cleared for marketing AND being used in accordance with its approved labeling?**
☐ Yes ☐ No (if no, proceed to question II. below)

a. **If yes,** what is the 510(k) clearance number or PMA number?: (proceed to question III. below)
**Attach a copy of the FDA generated letter; 510(k) clearance or PMA determination.

II. **If the device is *not* FDA approved or the study involves the investigational use of an FDA approved device, please complete the following questions:**

Has the sponsor submitted an IDE application to the FDA? ☐ Yes ☐ No

a. **If yes,** what is the IDE number for the device? IDE#:

Please support your IDE # by identifying which of following applies:

☐ The sponsor protocol has the IDE # listed on it
☐ I am providing a letter from the sponsor indicating the IDE # - please attach
☐ I am providing a letter from the FDA - please attach
☐ Other (e.g. correspondence from sponsor which references IDE #) - please attach

Please indicate the status of your IDE by identifying which of following applies:

☐ The IDE is active and the study can begin once IRB approval is obtained
☐ The IDE application was sent to and received by the FDA, but is not in effect
Please note: the study may not commence until the IDE is in effect
☐ Other – please explain:

b. **If no,** please indicate which of the following applies**:**

☐ I am providing a Letter from the sponsor stating that the study is a *non-significant risk device study*, which does not meet the definition of "significant risk device" under 21 CFR 812.3(m), and I am providing the basis for that determination - please attach
☐ I am providing a letter from the FDA granting an Investigational Device Exemption for the proposed use. - please attach
☐ I am providing a letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt. - please attach

III. **Does the device involve the use of ionizing radiation or isotopes?** ☐ Yes ☐ No

IV. **Will the Sponsor be charging the Principal Investigator and or Subject for the device?**
☐ No ☐ Yes **- If yes**, please describe or attach a rationale and a description of the amount to be charged:

Please provide a copy of the device manual that includes important components, ingredients, properties and principles of operation of the device and copies of applicable labeling.

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E.	**Is this study Federally funded?** ☐ Yes ☐ No **If yes**, what is your Federal-wide Assurance (FWA) number?: What federal agency is providing the funds? : Please explain if your FWA number is unavailable:		
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.	**Billing Information** – *please provide invoicing contact*		
	Contact Name:		
	Company Name:	**Phone:**	
	Address:	**Fax:**	
		Email:	
	Billing Reference / Purchase Order Number (if applicable):		
D.	**What are the phone numbers for subject use? – To be included in the consent form**		Mandatory - please ensure numbers are correct
	Phone:	**24 Hour Phone:**	
E.	**Will the PI be conducting study related activity at other locations?** ☐ No ☐ Yes – if yes, please indicate the number of additional locations: **If yes**, complete an 'Additional Study Location Form' for each location.		Include all locations for study related activities
F.	**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)?** ☐ No ☐ 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.		

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G.	**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?** ☐ No ☐ Yes (if yes, please complete a 'Financial Disclosure Form' for each individual with a financial interest) **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?** ☐ No ☐ Yes (if yes, please complete a 'Financial Disclosure Form' for each individual with a financial interest)	Interests that require disclosure are described in the Alpha IRB Financial Disclosure Form and in the IRB Guidebook
H.	**Has this study ever been submitted to another IRB for review?** ☐ No ☐ Yes **If yes**, list the name of the IRB(s) and the outcome of the review:	
I.	**Please indicate the human research participant protection training the Principal Investigator has completed within the past 3 years (Check all that apply):** ☐ 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 ☐ DIA, ACRP, or SOCRA Training and/or Certification ☐ CITI Program Courses (*Available through Alpha IRB*) - https://www.citiprogram.org/ ☐ OHRP Online Assurance Training Course - https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training ☐ Completion of self-study or other training specific to human research participant protection OR ☐ None	
J.	**If you checked self-study or other training specific to human research participant protection, please check all that apply:** ☐ Investigator Meetings ☐ Clinic/CRO/SMO Training (please describe): ☐ Web Based HRPP Training (please describe): ☐ Other (please describe):	
K.	**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):** *(Note: acceptable forms of training, such as those listed below, must be complete before full IRB approval is granted)* ☐ Investigator Meetings ☐ Clinic/CRO/SMO Training (please describe): ☐ Web Based HRPP Training (please describe): ☐ Other (please describe):	

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L.	**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?** ☐ Yes ☐ No **If no,** please describe how this will be addressed:	
M.	**Do any of the below apply to the PI involved with this study?** Been audited (inspected) by any regulatory agency (FDA, OHRP, etc.) in the last five (5) years? ☐ No ☐ Yes – attach documentation 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 at any time in the past? ☐ No ☐ Yes – attach documentation Been sanctioned by any IRB or had an IRB suspend or terminate a study for any reason at any time in the past? ☐ No ☐ Yes – attach documentation 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 at any time in the past? ☐ No ☐ Yes – attach documentation	Attach documents for all **'yes'** answers. (e.g. 483 & site response, FDA warning letter, letters from medical board, etc.)
N.	**How long has the PI been conducting human subjects research?** **Years Months**	
O.	**How many studies / clinical trials has the PI conducted in the past (as either a PI or Sub-I)?**	
P.	**Is the PI's human subjects research experience listed on his/her CV (Including specific study information and dates)?** ☐ Yes ☐ No – If no, describe the specific studies the PI has been involved in (include dates): ☐ N/A – no prior human subjects research experience	Include specific study info and dates. Attach additional pages, if needed
Q.	**How many studies is the PI currently involved in as a PI?** **How many studies is the PI currently involved in as a Sub-Investigator?**	
R.	**Number of clinical research staff the PI will supervise on this project:** **Sub-Is:** **Research Coordinators:** **Other staff (nurses, technicians, etc.):**	
S.	**Does the site have adequate resources, including staff and medical or psychosocial resources, to conduct this study?** ☐ Yes ☐ No - if no, explain:	

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T. **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)?

- 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.

☐ **Yes** ☐ **No – if no, please explain:**

☐ **N/A – this study does not involve study product**

U. **What resources are available at this site to treat emergencies, if they occur?**

☐ BLS certified personnel
☐ ACLS certified personnel
☐ Emergency response team within facility
☐ Other (please describe):
☐ Emergency medication
☐ Crash cart
☐ Access to 911
☐ N/A - emergency procedures are not applicable to this research. Please explain why:

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?**

Ethnicity: (must total 100%)

Hispanic or Latino:	%
Not Hispanic or Latino:	%

Race: (must total 100%)

White: %	Black or African American: %	Native Hawaiian or Other Pacific Islander: %
Asian: %	American Indian or Alaska Native: %	Other: %

Gender: (must total 100%)

Male:	%
Female:	%

Age: (must total 100%)

0 – 17:	%
18 – 64:	%
65 – >:	%

Will any gender or race/ethnicity be excluded from the study?

☐ No ☐ Yes – describe:

If yes, is this per the protocol? ☐ No ☐ Yes – provide the protocol section #:

If not per the protocol, please provide a justification for this/these exclusion(s):

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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?** ☐ No ☐ Yes – check all that apply below: ☐ State laws related to the use of Protected Health Information / HIPAA - please explain: ☐ California Experimental Subject's Bill of Rights ☐ Age of majority different than 18 - please explain: ☐ Other - please explain:	Attach copies of any relevant state laws, if applicable
C.	**Are there any community attitudes that may adversely affect subjects in this study?** ☐ No ☐ Yes **If yes**, describe attitudes and how they may affect subjects:	Describe on separate page if needed
4.	**VULNERABLE POPULATIONS**	
A.	**Do you intend to enroll any vulnerable populations?** ☐ **Yes – please select all that apply below** ☐ **No – proceed to section 5.** *(please include populations that are included in the protocol as well as those that may be enrolled based on your site's demographics)* ***Enrollment of a vulnerable population is not allowed unless first approved by the IRB***	Attach additional information if needed.

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B.	☐ **Children/minors** (note: 19 is the age of majority in Alabama and Nebraska; 21 is the age of majority in Puerto Rico.) • **What is the age range of the minor subject(s) you will be enrolling?**: • **Will children or minors without parents be enrolled?** ☐ **Yes** ☐ **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?** ○ 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 ☐ **Yes** ☐ **No – if no, please explain:**	Please provide copy of Assent Form (in Word document form)
C.	☐ **Non-English speaking** • **Do you agree to adhere to the following additional protections?** ○ 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 ☐ **Yes** ☐ **No – if no, please explain:** • **Into what language(s) will the Consent Form(s) and/or Study Materials need to be translated?:** • **Would you Alpha IRB to facilitate the translation of the Consent Form(s) and/or Study Materials?** ☐ **Yes** – please indicate which materials will need translation: ☐ **No** – the site will facilitate translation and provide copies of the translated materials, along with copies of certifications, to Alpha for approval prior to use.	All translated materials must be submitted to Alpha IRB for approval prior to use. All translated materials must be accompanied by a certification of accuracy.
D.	☐ **Economically disadvantaged** • **Do you agree to adhere to the following additional protections?** ○ 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. ☐ **Yes** ☐ **No – if no, please explain:**	

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E.	☐ **Employees of site, family members of site staff** • **Do you agree to adhere to the following additional protections?** ○ 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 ☐ **Yes** ☐ **No – if no, please explain:** *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.*	
F.	☐ **Illiterate/unable to read (including those with visual impairment)** • **Do you agree to adhere to the following additional protections?** ○ 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 ☐ **Yes** ☐ **No – if no, please explain:** *Note - an impartial witness signature line will be added to the site's informed consent form(s) (if not already included)*	
G.	☐ **Pregnant Women** • **Do you agree to adhere to the following additional protections?** ○ Individuals engaged in the research will have no part in: ▪ 1) any decisions as to the timing, method, or procedures used to terminate a pregnancy, and ▪ 2) determining the viability of the fetus; and ○ No inducements, monetary or otherwise, will be offered to terminate the pregnancy ○ I will obtain the consent of the father, if required ☐ **Yes** ☐ **No – if no, please explain:**	

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H.	☐ **Adults with diminished decision-making capacity / cognitively impaired subjects** *(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.)* • **Do you agree to adhere to the following additional protections?** ○ The subject will be assessed and the PI will determine whether they are competent to provide consent on their own behalf. ○ The subject will not be enrolled or continue in the study unless they provide ongoing, affirmative assent. ○ The site will ensure that the subject is not being unduly influenced to participate or to continue participation ○ The site will ensure a legally authorized representative (LAR) is used when appropriate, allowed by the protocol, and approved by Alpha IRB. *Note: If use of an LAR is approved, Alpha IRB will add additional LAR signature blocks to the consent form.* ☐ **Yes** ☐ **No – if no, please explain:** • **Please provide a description of how capacity for consent or assent will be determined:** • **Will subjects with legally authorized representatives* (LARs) be enrolled?** ☐ Yes ☐ No - **If no,** please explain: **If yes,** is use of an LAR acceptable per the protocol? ☐ Yes ☐ 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: *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.	The site/PI is responsible for knowing who can serve as a LAR in your state. Or submit on separate page
I.	☐ **Terminally ill patients** • **Do you agree to adhere to the following additional protections?** ○ 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 ☐ **Yes** ☐ **No – if no, please explain:**	
J.	☐ **Other Vulnerable Population(s) not listed above** • **Describe the population(s) and the additional protections that will be taken:**	Or submit on separate page

5.	**INFORMED CONSENT**	
	An IRB may approve a consent document that does not include, or alters, some or all of the elements of informed consent, or an IRB may waive the requirements to obtain informed consent (for research not regulated by the FDA). Provide justifications for the following questions for requesting a waiver of written informed consent.	

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A.	**Are you requesting Waiver or Alteration of Informed Consent?** (select only one) ☐ **No** ☐ **Yes – I am requesting a waiver of informed consent** ☐ **Yes – I am requesting an alteration of informed consent**	**If no, proceed to section B.** **If yes, provide detailed answers in the sections below.**	
	I.	**Why will a waiver or alteration of informed consent not adversely affect the rights and welfare of subjects?**	
	II.	**Why is it impracticable to carry out the research without a waiver or alteration of informed consent?**	
	III.	**Whenever appropriate, how will pertinent information be provided to the subjects after their participation?**	
	IV.	**Why does the proposed research present no more than *minimal risk to the subjects?** * Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	
	V.	**If you selected "Yes – I am requesting a waiver of informed consent" you may skip to Question 6. Otherwise, proceed to next question below.**	
B.	**Who will conduct the informed consent process with the potential subjects?** ☐ PI ☐ Sub-I ☐ Research Coordinator ☐ Other:		Check all that apply

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C.	**Will your process to obtain informed consent adhere to the following standards?** • 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. ☐ **Yes** ☐ **No – if no, please explain:**	
D.	**Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the Sponsor contract?** ☐ **Yes** ☐ **No** ☐ **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)**	
	☐ Direct advertising (ads, flyers, etc.) ☐ Investigator's patients ☐ Physician referrals	
	☐ Database of potential subjects ☐ Phone screening ☐ None	
	☐ Other:	
B.	If you checked **'Database of potential subjects'**, have these individuals given prior permission to be contacted? ☐ Yes ☐ No ☐ N/A	
C.	**Are recruitment and/or study materials being submitted at this time?**	All subject materials must be approved by Alpha IRB prior to use
	☐ **No –** proceed to section 7. ☐ **Yes –** the following materials are being submitted with this submission (select all that apply):	
	☐ Radio/TV Ad ☐ Phone Screen ☐ Website/Internet Ad	
	☐ Newspaper/Print Ad ☐ Bulletin Board/Flyer ☐ Letter/PSA	
	☐ Brochure/ Handout ☐ Subject Diary ☐ Reminder Card	

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	☐ Other:	
D.	**Will you require a partial waiver of authorization for screening or recruitment purposes?** ☐ No ☐ Yes - complete a 'Request for Partial Waiver of Authorization Form' 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.*	
7.	**PAYMENT TO SUBJECTS**	
A.	**Are subjects being compensated for their participation?** ☐ **Yes** - complete sections B – E below ☐ **No** – proceed to section 8.	
B.	**Subjects will be compensated as indicated below:**	You may list more than one visit number per line. Attach additional pages if needed.

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: $				

C.	**Form of Payment:** ☐ Check ☐ Cash ☐ Gift Certificate/Card – list type (e.g. Visa): ☐ Other:	
D.	**Will a 1099 be issued?** ☐ No ☐ Yes - **If yes**, select all that apply to protect confidentiality ☐ Mail to subject's address provided to our site ☐ Subject may receive from site with proper ID	
E.	**When will subject receive his/her compensation?** ☐ At each completed study visit ☐ At the subject's final study visit ☐ Within *<indicate #>* weeks of subjects final study visit ☐ Other – please describe:	Attach additional pages if needed.

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8.	**PRIVACY INFORMATION**		
	"Privacy Interests" – refers to the interest of individuals in being left alone, limiting access to themselves and limiting access to their information.		
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:	☐ Yes ☐ 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:	☐ Yes ☐ No*	
C.	**Will the study-related assessments and procedures be conducted in a private setting/location?** ***If no**, please provide an explanation:	☐ Yes ☐ No*	
D.	**Is there any additional provision at your site to protect the privacy of subjects?** ***If yes,** please describe:	☐ Yes* ☐ No	
9.	**CONFIDENTIALITY OF SUBJECT INFORMATION**		
	Medical records and research records are different. They are handled differently and are subject to different protection. *(this question relates to research data)*		
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:	☐ Yes ☐ 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:	☐ Yes ☐ No*	
C.	**Will identifiers be removed from study related information whenever feasible and as soon as possible?** ***If no**, please provide an explanation:	☐ Yes ☐ 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:	☐ Yes* ☐ No	

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E.	**Will personnel not directly related to the research have access to study records or data?** ☐ No ☐ Yes - **If yes**, check all that apply below) ☐ Billing Office ☐ Medical Records ☐ Hospital Personnel ☐ Other:	
10.	**SAFETY MONITORING INFORMATION**	
A.	**Is there a monitoring plan which describes provisions to monitor data to ensure subject safety included in the protocol?** ☐ Yes ☐ No **If yes,** provide the following: Protocol Section: Page #(s) : **If no,** please describe appropriate provisions to monitor data to ensure subject safety: Please note: the monitoring plan (whether in the protocol and/or described above) should 1) list the specific items that will be monitored for safety (e.g., adverse events, subject compliance with the protocol, etc.) and 2) indicate the frequency at which accumulated safety and data information will be reviewed in order to determine the study remains safe and by whom (PI, medical monitor, etc.)	
B.	**Is there a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) for this study?** ☐ Yes ☐ No **If Yes,** do you agree to submit summary reports to Alpha IRB when available? ☐ Yes ☐ No – explain:	
11.	**DOCUMENT DISTRIBUTION** ***- ALL APPROVAL DOCUMENTS ARE EMAILED UNLESS OTHERWISE STATED BELOW. IF EMAIL IS ACCEPTABLE, LEAVE THIS SECTION BLANK***	All approvals will also be accessible online via Alpha IRB's OASIS
A.	Billing Reference / Purchase Order Number (if applicable):	
B.	☐ Standard Overnight ☐ 2-Day ☐ Other:	
C.	**Service Provider:** ☐FedEx ☐ UPS ☐ Other:	
D.	**Account No.:** **Reference No.:**	

1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
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SITE SUBMISSION FORM (SINGLE SITE)

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.alphairb.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 questions 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 require 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 regulatory 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.

Alpha IRB
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SITE SUBMISSION FORM (SINGLE SITE)

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:** _____

STUDY CHECKLIST

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

ALL STUDIES

☐ Final Protocol

☐ Study/Recruitment Material(s): ☐ Ads ☐ Screening Forms ☐ Diary ☐ Questionnaires ☐ Scales ☐ Other

☐ Sample Informed Consent Form(s) (in Word Format) : ☐ Main ☐ Genetic ☐ Assent ☐ Sub-study ☐ Other

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

☐ Principal Investigator's License(s)

☐ Additional Study Location Form(s)

☐ Financial Disclosure Form(s)

☐ Request for Partial Waiver of Authorization Form

DRUG / BIOLOGIC / DIETARY SUPPLEMENT STUDIES - Please also include the following (as applicable):

☐ Clinical Investigator's Brochure(s) (IND Studies)

☐ Package Insert / Package Label / Product Information (studies involving FDA approved drugs)

☐ IND # Support (question 1.C.II.a.)

OR ☐ Explanation or letter from the FDA - If IND exempt (question 1.C.II.b.)

☐ 1572 (optional)

DEVICE STUDIES – Please also include the following (as applicable):

☐ Device Manual(s)

☐ Copy of the FDA generated 510(k) clearance letter or PMA determination (question 1.D.I.a.)

OR ☐ IDE # Support (question 1.D.II.a.)

OR ☐ Letter from Sponsor with basis for *non-significant risk device study* (question 1.D.II.b.)

OR ☐ Explanation or letter from the FDA - If IDE exempt (question 1.D.II.b.)

Also for Device Studies, please ensure these elements are included in your protocol or submission:

Protocol includes a statement of the name, purpose and intended use of the device along with objectives and duration of the investigation; protocol supported risk analysis of all subjects; device manual includes a description of the device that includes important components, ingredients, properties and principles of operation of the device and copies of all applicable labeling; written procedures for monitoring device and its safe use; and any additional written reports on prior investigation conducted with the device.