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

SPONSOR / CRO STUDY APPLICATION

Complete this form when submitting a multi-center study. *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 following applies:
- ☐ The investigation meets the criteria at § 21 CFR 312.2(b). 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.

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

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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 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:		
F.	**How many total sites will be involved in this study?**		
G.	**How many sites will be utilizing Alpha IRB as their review board?**		
H.	**What is the anticipated date of the first site submission? / /**		
I.	**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:		
2.	**SPONSOR INFORMATION**		
A.	**Contact Name:**		
	Address:	**Phone:**	
		Fax:	
		E-mail:	
	Will a Contract Research Organization (CRO) be involved in this study? ☐ No ☐ Yes - if yes, provide information below		
B.	**CRO INFORMATION (IF APPLICABLE)**		
	Contact Name:		
	Position/Title:		
	Company Name:	**Phone:**	
	Address:	**Fax:**	
		Email:	
C.	**BILLING INFORMATION** – ***PLEASE PROVIDE INVOICING CONTACT.***		
	☐ **Same as Sponsor**	☐ **Same as CRO**	☐ **Other:** *Supply information below*
	Contact Name:		
	Company Name:	**Phone:**	
	Address:	**Fax:**	
		Email:	
	Billing Reference / Purchase Order Number (if applicable):		

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3.	**SUBJECT ENROLLMENT INFORMATION**	
A.	**What is the subject enrollment goal for the study/protocol?** **What are the anticipated dates for the following events?** **First subject enrolled:** **Last subject enrolled:** **Last subject completed:**	
B.	**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):	
4.	**VULNERABLE POPULATIONS**	
A.	**Does the <u>protocol design</u> require/include the enrollment of any vulnerable populations?** ☐ **Yes –** please select all that apply below ☐ **No –** proceed to section 5. ☐ Children/minors* ☐ Nursing home residents/institutionalized individuals ☐ Adults with diminished decision-making capacity ☐ Terminally ill patients ☐ Economically disadvantaged ☐ Non-English speaking ☐ Fetuses/fetal material ☐ Pregnant women ☐ Prisoners ☐ Homeless ☐ Illiterate/unable to read (including those with visual impairment) ☐ Other: *note: 19 is the age of majority in Alabama and Nebraska; 21 is the age of majority in Puerto Rico.	
B.	**Are there additional safeguards included in the protocol to protect the rights and welfare of these subjects?** ☐ Yes ☐ No **If yes,** provide the following: Protocol Section: Page #(s) : **If no,** please describe the additional safeguards that will be taken to protect the rights and welfare of these subjects (if site specific, please indicate so):	
C.	**If the study will enroll adults with diminished decision-making capacity / cognitively impaired subjects, will subjects with legally authorized representatives* (LARs) be enrolled?** ☐ No ☐ Yes ☐ N/A **If yes,** is use of an LAR acceptable per the protocol? ☐ Yes ☐ No - explain: **If yes**, provide justification for use of LARs in this study: <u>Please note:</u> sites will be required to provide justification in terms of state law or a decision by legal counsel of who constitutes an LAR in their 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.	Or submit on separate page
D.	**If the study will enroll children/minors, what is the allowable age range of the minor subject(s) to be enrolled per the protocol?**: *or* ☐ N/A <u>Please note:</u> Alpha IRB requires that children over the age of 7 must agree to participate in the research and provide written assent using the IRB approved assent form.	Please provide copy of Assent Form (as a Word doc)

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E.	**If non-English speaking subjects will be enrolled, into what language(s) will the Consent Form(s) and/or Study Materials need to be translated:** **Would you like 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 Sponsor/site will facilitate translations and will provide copies of the translated materials, along with copies of certifications, to Alpha for approval prior to use. ***Please note:*** *All translated materials must be accompanied by a certification of accuracy*	All translated materials must be submitted to Alpha IRB for approval prior to use.
5.	**SUBJECT RECRUITMENT AND ADVERTISING**	
A.	**Will a centrally coordinated advertisement program be used?** ☐ **No** ☐ **Yes**	
B.	**What methods will be used 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:	
C.	If you checked **'Database of potential subjects'**, have these individuals given <u>prior permission</u> to be contacted? ☐ Yes ☐ No ☐ N/A	
D.	**Are recruitment and/or study materials being submitted at this time?**	
	☐ **No –** proceed to section 6. ☐ **Yes –** the following materials are being submitted with this submission (select all that apply):	All subject materials must be approved by Alpha IRB prior to use
	☐ Radio/TV Ad ☐ Phone Screen ☐ Website/Internet Ad	
	☐ Newspaper/Print Ad ☐ Bulletin Board/Flyer ☐ Letter/PSA	
	☐ Brochure/Handout ☐ Subject Diary ☐ Reminder Card	
	☐ Other:	
E.	**Is the Sponsor allowing sites to submit site specific subject recruitment materials for IRB review?** ☐ Yes ☐ No	
F.	**Will sites require a partial waiver of authorization for screening or recruitment purposes?** ☐ No ☐ Yes - complete a 'Request for Partial Waiver of Authorization Form' <u>Please note:</u> 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 utilizing a phone screen, you may be required to submit a partial waiver request in order to use/disclose PHI.*	
6.	**PAYMENT TO SUBJECTS**	
A.	**Are subjects being compensated for their participation?** ☐ **Yes** - complete section B. below ☐ **No** – proceed to section 7.	

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B.	**Indicate which of the following applies:** ☐ Sites will determine their own compensation amounts and schedule of disbursement ☐ All sites must follow the same compensation schedule which is outlined in the Sponsor's template consent form		
7.	**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.	**Are there any additional provisions to protect the privacy of subjects?** ***If yes,** please describe:	☐ Yes* ☐ No	
8.	**CONFIDENTIALITY AND HIPAA INFORMATION**		
	"Confidentiality" refers to individual's wishes as to how his/her identifiable private information will be handled, managed, and disseminated. Confidentiality is a means of protecting that information, usually by safeguarding it from unauthorized disclosure.		
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?** ***If no**, please provide an explanation:	☐ Yes ☐ No*	
D.	**Are there any additional provisions to protect the confidentiality of subject information?** ***If yes,** please describe:	☐ Yes* ☐ No	

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9.	**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 the 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,** does the Sponsor agree to submit summary reports to Alpha IRB when available? ☐ Yes ☐ No – explain:
C.	**Site Monitoring Information:** How frequently will Sponsor/CRO representatives visit the research sites for routine monitoring?: How frequently will Sponsor/CRO representatives speak with the research sites via telephone: Please briefly explain the criteria for For-Cause On-site Visits:
D.	**IND Safety Reports / Adverse Device Effect Reports:** Alpha IRB accepts "external reports" such as IND Safety Reports, MedWatch Reports, SUSAR Reports, CIOMS Reports and Adverse Device Effect Reports that are determined by the Sponsor to represent an "Unanticipated Problem involving risk to participants or others" or an "Unanticipated Adverse Device Effect Report." For these reports to be reportable, the event(s) must indicate a new or increased risk of harm to subjects or others. Alpha IRB recognizes that the Sponsor is in a better position to process and analyze adverse event information for the entire study and to assess whether an external adverse event occurrence is an unanticipated problem involving risk to participants or others or an Unanticipated Adverse Device Effect Report. External Reports submitted by the Sponsor/CRO that are **not** indicated to be an "Unanticipated Problem involving risk to participants or others" or an "Unanticipated Adverse Device Effect Report will receive an acknowledgement of receipt. The Sponsor/CRO is responsible for providing copies of the receipt acknowledgement to individual sites. ***For an additional fee, Alpha IRB can provide site-specific acknowledgment letters for external events to each individual site.***
10.	**COMPENSATION AND MEDICAL CARE FOR RESEARCH RELATED INJURY**
	Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the investigators site's contracts? ☐ Yes ☐ No - **If No, please explain:**

11.	**DOCUMENT DISTRIBUTION** - ***ALL APPROVAL DOCUMENTS ARE EMAILED TO SPONSOR AND SITES UNLESS OTHERWISE STATED BELOW. IF EMAIL IS ACCEPTABLE, LEAVE THIS SECTION BLANK***		All approvals will also be available online via Alpha IRB's OASIS
A.	☐ Standard Overnight ☐ 2-Day ☐ Other:	**Provider:** ☐ FedEx ☐ UPS ☐ Other:	
B.	**Account No.:**	**Reference No.:**	

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By signing below the Sponsor agrees to and affirms compliance with the following terms:

The Sponsor/CRO is responsible for selecting only qualified investigators, with sufficient time to conduct the research properly and the appropriate potential to recruit the required number of suitable subjects, as appropriate experts to conduct the research study. Sponsors/CROs must comply with all requirements regarding research activities, including federal, state, local and IRB requirements. Only complete and accurate information should be submitted to the IRB for review and approval.

Sponsor must evaluate and ensure that the appropriate resources and infrastructure to support the conduct of clinical research are maintained at the sites. The sites must be in compliance with the Sponsor's requirements for handling medical emergencies. The sites must store research records in such a way to protect the privacy and confidentially of subject information.

Each Sponsor/CRO should ensure that the manufacture and formulation of the investigational product conforms to federal regulation. If the study will utilize a comparator, ensure that manufacture and formulation of the comparator also conforms to federal requirements. Each Sponsor/CRO should also ensure the appropriate control (storage, dispensation, and accountability) of the investigational product at the sites as required by federal, state, and local law.

Sponsor/CRO (and/or Principal Investigators) must promptly notify Alpha IRB of any unanticipated problems involving risk to human subjects or others, any significant deviations from the protocol that adversely affects the safety, rights or welfare of subjects or others, or the integrity of the study data and any findings of study monitors that could affect the safety of participants or influence the conduct of the study. The Sponsor/CRO must also notify Alpha IRB of any study results, obtained as part of the study or for two (2) years after the study has closed, that could directly affect participant safety. These notifications to the IRB must occur promptly and no later than ten (10) business days from the time of identification of the event or finding. All results from the research study that affect the subject safety or medical care will be communicated to study participants in writing through the Sponsor/CRO or the investigator.

If applicable, the Sponsor/CRO must submit data and safety monitoring board (DMSB) reports to the investigators and Alpha IRB. Urgent DSMB reports (e.g. reports indicating an unanticipated problem involving risk to subjects or others) must be reported to the Alpha within ten (10) business days of the Sponsor/CROs' receipt of the report. Routine reports may be submitted at the time of continuing review.

The Sponsor/CRO must ensure by adequate site selection methods and ongoing monitoring that the study staff at the research sites are conducting research in compliance with regulatory and IRB requirements including the policies set forth in the current Alpha IRB Investigators Guidebook (available online at www.alphairb.com).

Signature: _____ **Date:** _____
(Sponsor/CRO Authorized Representative)

Printed Name: _____

Title: _____ **Company:** _____

To guarantee your study will be reviewed at the next available Board meeting, documentation will need to be received by the submission deadline. *See Board Meeting Calendar at **www.alphairb.com**.*

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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

☐ 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.