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 (MULTI-CENTER)

We accept study submissions by email, fax or mail.

1.	**STUDY INFORMATION**		
A.	**Sponsor:**	**Protocol No.:**	
B.	**Study Title:**		
C.	**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.	**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:**	
D.	**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
E.	**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

If yes, UNC FWA#: 4801

You should answer "yes" if you are conducting the study at both UNC Hospitals and off-campus clinic.

Even though you already addressed COI disclosure through UNC, you must also complete this section. Contact your investigator(s) for information to complete this section.

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Mark "no". Although UNC IRB has seen this study, it is not being reviewed for these purposes.

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F.	**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:	
G.	**Please indicate the human research participant protection training the Principal Investigator has completed within the past 3 years (Check all that apply):** ☐ Review of GCP Guidelines, relevant FDA Information Sheets, and the Belmont Report ☐ DIA, ACRP, or SOCRA Training and Certification ☐ Completion of the CITI Program: Course in Human Research Subjects Protections (*Available through Alpha IRB)* ☐ Completion of National Institutes of Health (NIH) Training: NIH Clinical Center Clinical Research Training or NIH Office of Extramural Research Protecting Human Research Participants Training. ☐ Completion of self-study or other training specific to human research participant protection OR ☐ None	
H.	**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 ☐ Web Based HRPP Training (please describe): ☐ Other (please describe):	
I.	**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 ☐ Web Based HRPP Training (please describe): ☐ Other (please describe):	
J.	**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:	
K.	**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 5 years? ☐ No ☐ Yes – attach documentation Been sanctioned by any IRB or had an IRB suspend or terminate a study for any reason? ☐ No ☐ Yes – attach documentation Been disciplined by a public or private medical organization, disciplined 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? ☐ No ☐ Yes – attach documentation	Attach documents for all **'yes'** answers. (e.g. 483 & site response, FDA warning letter, letters from medical board, etc.)

Check "yes" for CITI program as all UNC researchers are required to take Ethics (IRB) modules

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L.	**How long has the PI been conducting human subjects research?** **Years or Months**	
M.	**How many studies / clinical trials has the PI conducted in the past (as either a PI or Sub-I)?**	
N.	**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
O.	**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?**	
P.	**Number of clinical research staff the PI will supervise on this project:** **Sub-I's:** **Research Coordinators:** **Other staff (nurses, technicians, etc.):**	
Q.	**Does the site have adequate resources, including staff and medical or psychosocial resources, to conduct this study?** ☐ Yes ☐ No - if no, explain:	
R.	**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): ☐ N/A; explain: ☐ Emergency medication ☐ Crash cart ☐ Access to 911	
S.	**Name of the nearest emergency facility to be used in the event of an emergency:** **Distance to emergency facility from this study site:** miles	

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3. SUBJECT INFORMATION

A. What is the diversity of your research population?

Race and Ethnicity: (must total 100%)

White: %	Hispanic or Latino: %	Black or African American: %	Native Hawaiian or Other Pacific Islander: %
American Indian or Alaska Native: %	Asian: %	Middle Eastern: %	Other: %

Gender: (must total 100%)

Male: %
Female: %

Age: (must total 100%)

0 – 18: %
19 – 64: %
65 – >: %

To access data for this section, copy and paste web address for US Census Bureau into your browser: http://quickfacts.census.gov/qfd/states/37000.html

Totals should equal 100%.

B. Are there any state or local laws that you are aware of that might impact or influence the conduct of the study?

Attach copies of any relevant state laws, if applicable

☐ No ☐ Yes – check all that apply below:

☒ State laws related to the use of Protected Health Information (PHI) - please explain:
☐ California Experimental Bill of Rights
☐ Mandatory IRB site visits /on-site reviews - please explain:
☐ Age of majority different than 18
☒ Other - please explain:

Upload copy of "North Carolina State Laws Governing Clinical Research" provided in General Documents folder

C. Are there community attitudes that may adversely affect subjects in this study?

Describe on separate page if needed

☒ No ☐ Yes

If yes, describe attitudes and how they may affect subjects:

4. VULNERABLE POPULATIONS

A. Do you intend to enroll any vulnerable populations?

Attach additional information if needed.

☐ **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 sites demographics):

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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 you will be enrolling?**: • **Will children or minors without parent 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?** 18 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 will not be unduly influenced to participate ☐ **Yes** ☐ **No – if no, please explain:**	Please provide copy of Assent Form 18 is the legal age in NC
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 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?** ☐ **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.	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** • **Do you agree to adhere to the following additional protections?** ○ The investigator will make known to employee(s) that their participation in this study is strictly voluntary and their decision to participate, or not to participate, will have no impact on their performance evaluations, job advancement, or employment status ○ Measures will be taken to ensure the confidentiality of an employee's study-related records ☐ **Yes** ☐ **No – if no, please explain:**	
F.	☐ **Illiterate/unable to read (including those with visual impairment) - If this box is checked, an impartial witness signature line will be added to the informed consent form (if not already included)** • **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:**	
G.	☐ **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:**	

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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?** ○ Assent will be solicited from subjects with limited decision making capacity ○ The subject will be periodically re-consented to ensure their continued involvement is voluntary ○ 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, required by the protocol, or required by Alpha IRB ☐ **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?** ☐ No ☐ Yes **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.	☐ **Other Vulnerable Population(s) not listed above (pregnant women, fetuses, neonates, prisoners, etc.)** • **Describe the population(s) and the additional protections that will be taken:**	Or submit on separate page

If yes, refer to SOP Section 28.11.2, "North Carolina State Laws Governing Clinical Research", previously uploaded

5.	**INFORMED CONSENT**	
A.	**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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B.	**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 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, 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). • If the subject agrees to participate, the consent form 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 the signed and dated consent form to take home. ☐ **Yes** ☐ **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?** ☐ **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 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) ☐ **No – Proceed to section 7.** ☐ **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:	

You may need to mark "no". The UNC IRB permission letter details the required subject injury language. Make appropriate changes to the ICF. Describe here.

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If "yes", upload UNC IRB approval letter which indicates that it will serve as HIPAA privacy board. Your request for a partial waiver of HIPAA for recruitment will be reviewed by the UNC IRB

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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 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:				
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.

C. **Form of Payment:**
☐ Check ☐ Cash ☐ Gift Certificate/Card – list type (e.g. Visa): ☐ Other:
☐ Reimbursement only (Reimbursements for costs incurred such as travel expenses, parking fees, etc.). If reimbursement, will subject be required to submit proof of expenses? ☐ No ☐ Yes

D. **Will a 1099 be issued?**
☐ No ☐ Yes - **If yes**, select all that apply to protect confidentiality
☐ Mail to subjects address provided to our site
☐ Subject may receive from site with proper ID

If compensation payments > $200/calendar year, check "yes" AND check "Mail to subjects address provided to our site".
Note: You will need to use UNC SSN form with subjects as described in UNC IRB approval letter.

E. **When will subject receive his/her compensation?**
☐ At each completed study visit
☐ At the subjects 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:	☐ No ☐ Yes	
B.	**Will subjects' personal information be collected in a private setting/location away from the public (when applicable)?** **If no**, please provide an explanation:	☐ No ☐ Yes	
C.	**Will the study-related assessments and procedures be conducted in a private setting/location?** **If no**, please provide an explanation:	☐ No ☐ Yes	
D.	**Is there any additional provision at your site to protect the privacy of subjects?** **If yes,** please describe:	☐ No ☐ Yes	

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.	**Please indicate the provisions to maintain subject confidentiality:** (check all that apply)		
	☐	Paper based records will be kept in a secure location and only accessible to personnel involved with the study.	
	☐	Computer based files will be password protected and only be made available to personnel involved with the study.	
	☐	Study personnel will be required to sign statements agreeing to protect the security and confidentiality of study information prior to being granted access to any related information.	
	☐	When feasible, identifiers will be removed from study related information.	
	☐	Other, please provide an explanation:	
B.	**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:		

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

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I certify that the information provided in the application is true and correct. My signature below indicates that I will comply with my responsibilities as Principal Investigator, as outlined above for the protection of human subjects.

Printed Name Principal Investigator: _____

Signature Principal Investigator: _____ **Date:** _____

SITE CHECKLIST

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

- ☐ Principal Investigator's CV
- ☐ 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

Changes should include UNC subject injury and COI language. See IRB permission letter and COI Finalization Letter (email) for details on changes to make. Also, remove HIPAA language as UNC will approve a separate HIPAA authorization form (as detailed in UNC permission letter).