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

www.alphairb.com

REQUEST FOR PARTIAL WAIVER OF AUTHORIZATION FOR RECRUITMENT

Under the HIPAA Privacy Rule, use or disclosure of an individual's protected health information (PHI) by a covered entity for research purposes requires the individual's written authorization, unless a waiver or partial waiver of authorization is granted by an IRB / Privacy Board, in which case, such authorization may be given orally by the individual. A partial waiver does not eliminate the investigator's responsibility to obtain written informed consent and/or authorization from the individual prior to study enrollment. [45 CFR 164.512]

Instructions: please complete the form in its entirety and attach a copy of the data collection tool (phone screen form, internet screen form, etc.), if not already submitted.

1. GENERAL INFORMATION	
Sponsor:	**Protocol Number:**
Protocol Title:	

This waiver is being submitted for the following (choose only one):

- ☐ Study wide – this will apply to all sites in the study
- ☐ Site – this applies only to the following site (complete PI/site info below)

Principal Investigator:	**Phone:**
Primary Site Name:	**E-mail:**
Contact person:	**Phone:**
Position/Title:	**E-mail:**

2. Please specify for which recruitment method(s) this waiver is being requested? Check all that apply:

- ☐ Phone screening
- ☐ Internet screening
- ☐ Create a record containing PHI, with potential study subject's verbal permission
- ☐ Other - please describe:

3. Who will have access to the PHI obtained? Check all that apply:

- ☐ Principal Investigator
- ☐ Sub-Investigators
- ☐ Study Coordinators
- ☐ Other Site Staff - please describe:
- ☐ SMO / Sponsor / CRO or other third party - Please describe:

Alpha IRB

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4. Please specify which identifiers you propose to use or disclose under this waiver. Check all that apply:

☐ Names	☐ Account numbers
☐ Addresses	☐ Certificate/license numbers
☐ Telephone and/or fax numbers	☐ Device identifiers and serial numbers
☐ Email addresses	☐ Web Universal Resource Locators (URLs)
☐ Social security numbers	☐ Internet Protocol (IP) address numbers
☐ Medical record numbers	☐ Biometric identifiers, including finger and voice prints
☐ Health plan beneficiary numbers	☐ Full face photographic images and any comparable images
☐ Dates directly related to an individual, i.e., birth date, admission date, discharge date, date of death (only the year may be included)	☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ For individuals over 89, all elements of dates (including year) indicative of such age (except where aggregated into a single category of age 90 or older)	☐ Any other unique identifying number, characteristic, or code – please describe:

5. Please specify the source of the PHI that will be used. Check all that apply:

☐ Medical / medication history	☐ Hospital /medical/clinic/physician records
☐ Demographic info (gender, race, age, etc.)	☐ Mental health records
☐ *Verbal* medical / medication history	☐ Lab, pathology and/or radiology reports/results
☐ *Verbal* Demographic info (gender, race, age, etc.)	☐ Other – please describe:

6. Is this PHI the minimum necessary for the purposes of the research?

☐ Yes ☐ No - If no, please explain:

7. Plan to protect potential subjects from improper use/disclosure of their PHI

If PHI obtained will be kept on paper, will the paper documentation be stored in a secure, locked area with limited access? ☐ Yes ☐ No - If no, please explain:

If PHI obtained will be entered into an electronic database, will the PHI have limited access and password protection? ☐ Yes ☐ No - If no, please explain:

Indicate any additional measures to protect PHI from improper use and disclosure by checking all that apply:

☐ Confidentiality agreements with study staff
☐ Policies and procedures relating to privacy and confidentiality
☐ Other – please describe:
☐ N/A

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8. When will the identifiers collected/recorded be destroyed? Check all that apply:

(Identifiers must be destroyed at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.)

☐ PHI will be destroyed immediately upon the individual's request

☐ PHI will be retained until potential subjects come to the study site to sign a HIPAA Authorization and complete screening

☐ PHI will be destroyed with the study records

☐ PHI will not be destroyed. Please specify a health or research justification for retaining the PHI below:

- ☐ With the subject's verbal permission, PHI will be kept in a confidential database for possible qualification in future research studies
- ☐ Other – please describe:

9. Why it is not practicable to conduct the proposed research activities without the Waiver? Check all that apply:

☐ Potential subjects will be contacting the site by telephone and will not be able to sign a HIPAA Authorization

☐ Other – please describe:

10. Why it is not practicable to conduct the proposed research without access to and use of the PHI? Check all that apply:

☐ Review of the PHI is necessary to determine whether prospective subjects are eligible for this study

☐ Other – please describe:

By signing this form, I am providing written assurance that only the minimum necessary PHI to the research activity will be used or disclosed as described in this request; access to the information will be limited to the greatest extent possible; and the PHI will not be reused or disclosed to any other person or entity, except as required by law.

Principal Investigator Printed Name

Principal Investigator Signature: Date

If this form was completed by the Sponsor / CRO, please complete the following:

Name of Individual Completing This Form

Company / Title

Signature: **Date**