ALUNG TECHNOLOGIES, INC. APPLICATION FOR AN INVESTIGATOR-SPONSORED RESEARCH PROJECT

Please attach your current, signed curriculum vitae (CV), the separate research protocol proposal and budget (when applicable), and send all materials to Alethea Wieland, Director of Clinical Affairs, by email (awieland@alung.com) or fax (+49 89 92185817).

1. Name of Investigator:	
2. Email of Investigator:	3. Phone Number of Investigator *(+country code):*
4. Name and Address of Investigator's Hospital or Research Center:	
5. Proposed Title of Clinical Research Project:	
6. Study Population:	
7. Primary Hypothesis:	
8. Primary Endpoint(s):	
9. Secondary Endpoint(s):	
10. Key Inclusion Criteria:	
11. Key Exclusion Criteria:	
12. Relevant Publications / Study Results:	
13. Number of Participating Centers *(list in the protocol)*:	14. Anticipated Enrollment Rate Per Site Per Month:
15. Anticipated Enrollment Start Date:	16. Anticipated Enrollment Stop Date:
17. Anticipated Total Number of Subjects:	18. Length of Time Each Subject in Trial *(time from enrollment through follow-up)*:
19. Anticipated Time to Perform Data Analysis and Report Generation:	20. Anticipated Publication Submission Date:

21. Study type *(check all that apply):*

☐ Non-investigational *(uses current indication for severe COPD patients failing NIV or lung protective ventilation)*

☐ Investigational *(tests a new indication not yet approved)*

☐ Pilot/Feasibility *(≤ 20 subjects)*

☐ Pilot-to-Pivotal *(pilot phase within a pivotal)*

☐ Pivotal

☐ Post-Market

☐ Prospective

☐ Retrospective

☐ Observational

☐ Randomized, Controlled (control is standard of care or no treatment)

☐ Single arm

☐ Historical case-matched

☐ Hemolung RAS Registry dataset

☐ Economic Impact

☐ Open-label

☐ Blinded

☐ Case-series

☐ Quality of Life Measures

☐ Survey

☐ Meta-analysis

☐ Other *(describe)*:

22. Funding being sought *(check all that apply):*

☐ I will support the study in full and will not need additional support from ALung.

☐ I am seeking full grant support from (_____). The date I will obtain the funding decision is (_____).

☐ I am seeking partial grant support from (_____). The date I will obtain the funding decision is (_____).

☐ I am seeking only support from ALung for the equipment and consumables for (_____) total subjects.

☐ I am seeking additional support from ALung for the total amount of (_____) (describe currency).
(List details of costs you are requesting from ALung or send a separate itemized budget.)

_____
_____
_____.

23. Request for additional ALung resource support *(check all that apply):**

☐ Provide training and Instructions for Use (IFU) on the device

☐ Comments on study design

☐ Development of template informed consent materials

☐ Guidelines on adverse event reporting to ALung

☐ Assistance with Regulatory Submission *(describe)*:

☐ Assistance with Ethics Committee or Institutional Review Board Submission *(describe)*:

☐ Other *(describe)*:

***ALung does not provide resources to design the study or develop the protocol and case report forms; monitor or conduct the study; and, perform statistical analysis or medical writing.**

24. Do you have an institutional clinical trial agreement for this clinical research project?

☐ Yes ☐ No

25. Do you have plans to form a data safety monitoring board (DSMB) or Clinical Events Committee (CEC) for this clinical research project *(required especially for investigational trials for new indications)*?

☐ Yes ☐ No ☐ Not applicable

26. Do you have plans to use the Hemolung RAS in a commercial setting prior to enrolling subjects in this clinical research study? ☐ Yes ☐ No ☐ Not applicable

If yes, in how many patients?

27. Do you ensure this study will be conducted under rigorous scientific and ethical standards, applicable laws and regulations, IRB/EC approval, good clinical practices (GCPs), good clinical data management practices (GCDMPs), International Committee of Medical Journal Editors (ICMJE) guidelines, and that reporting of all serious adverse events (SAEs) will be submitted to ALung and regulatory agencies (when applicable) in a timely manner?

☐ Yes ☐ No

28. Additional Comments: