

A-LIST Operating Principles

OVERVIEW

- A-LIST is a diverse online community of people living with Alzheimer's and other dementias* and caregivers who are committed to delivering their voices to develop a growing understanding of how Alzheimer's affects people's lives.
- A-LIST's purpose is to generate for the field new insights into what matters most to those at risk for, living with, or caring for someone with Alzheimer's.
- To achieve this purpose and assure its strategic growth, A-LIST has developed, in consultation with internal and external advisors, these Operating Principles that will guide A-LIST's delivery of new research projects.
- At the core of these Operating Principles are: UsA2's recognition of the essential contribution that members of the A-LIST are making to develop this new national resource; A-LIST's commitment in return to conduct trustworthy research that is shared widely; and AD PACE's organizing goal of advancing the understanding of Alzheimer's and its effects on the lives of those affected by this devastating disease.

* Whenever the term 'patient' is used in the context of AD PACE, the term is intended to apply to persons living with Alzheimer's and other dementias for whom being a 'patient' is one role and only one role among many that such individuals assume as they lead rich and complex lives. It is never intended to define the individual.

OPERATING PRINCIPLES

1. **The A-LIST conducts research projects in accordance with the A-LIST's IRB approved protocol, *The A-LIST What Matter Most Insights Series*.** Operating under the review of an IRB offers immense value to patient and caregivers who are participating in the A-LIST as well as to UsA2 as the sponsor of the A-LIST Insights Series Study. Such review provides, among other values, independent assurance that A-LIST research projects are conducted with the highest levels of ethical compliance and protections for participant privacy and data security. Experienced and qualified A-LIST professionals act as Principle Investigator and supporting researchers. In these roles these individuals will provide final approval of research projects, including survey instruments, data collections, and public announcements, assuring alignment with these Operating Principles and the A-LIST Insights Series Study protocol. To protect participant privacy, investigators associated with a sponsor of a research project will have access only to de-identified participant level data and, where appropriate, the sponsor will execute a nondisclosure agreement providing further protections for participant privacy and data security.
2. **A-LIST will strive to assure that all of its research projects are free from bias or undue influence.** The A-LIST team develops surveys based on decades of experience with aim to advance knowledge that is trust-worthy. As an additional step to assure that A-LIST research projects are free from bias or undue influence, A-LIST convenes a panel composed of individuals who are at risk, who have a diagnosis, or who are caregivers, together with scientific advisors that provides a second level of review, when requested, of survey contents prior to programming of key surveys.

- 3. Decisions to undertake an A-LIST research project will be made taking into consideration multiple factors:**
 - Will the research project advance the interests of persons living with the disease?
 - Will the information generated by the research add to the base of knowledge being developed by the A-LIST?
 - Will the research project build the credibility of the A-LIST, engender trust, and deliver a sense of contribution among the A-LIST participants?
 - Is the area of interest a priority for the A-LIST and UsA2?
 - Is the information sought duplicative of prior research?
 - Does undertaking the research project pose any risk to the reputation of A-LIST, AD PACE, or UsA2, and has due diligence been undertaken to assure against any such risk?
 - Is there capacity and adequate funding to conduct the work? Consideration will be given to staff availability based on current survey commitments, as well as balance of funding for new and existing expenses related to a proposed project.
- 4. Results from any A-LIST research project will be made public in poster, manuscript form, or otherwise, not later than 12 months following completion of the research project.** Any exceptions must be approved by A-LIST at project onset or at the time the sponsor of the research project first becomes aware that the 12-month publication requirement cannot be met. Further, A-LIST expects the sponsor of a research project to: (i) provide updates on the status of the research project during its course; and (ii) submit to A-LIST all findings from research project at its conclusion.
- 5. All underlying de-identified data will be deposited in the AD PACE Data Commons within 12 months of research study completion or upon publication, whichever shall first occur.** This requirement applies to all studies, whether published or not, and whether the reason not to publish is due to the absence of a viable publication opportunity or a decision not to publish by the sponsor of the research project. Accordingly, study data from studies that are not published will also be de-identified and added to the AD PACE Data Commons. Further, some data may not be appropriate for publication but may be disseminated in less formal ways (e.g., by UsA2 through the A-LIST's Pulse of the Community or through a UsA2 or a sponsor's blog post). The A-LIST team and the sponsor of a study will each be afforded the advance right to review and approve such communications.
- 6. A-LIST researchers will be co-authors on any publication of results from an A-LIST research project, in accordance with ICMJE guidelines.**
- 7. When A-LIST is working with an industry sponsor of a research project, and before the project findings are published, A-LIST will work to achieve an appropriate balance of transparency and confidentiality.**
 - As part of the initial contract for a research project (i.e. before work-order/purchase order is executed), the sponsor of any research project will approve a high-level, short "Project Summary" of the research project intended for public disclosure.
 - The Project Summary will be used by A-LIST in public reports on its ongoing work and in discussions with other sponsors on new requests.
 - A-LIST will take reasonable steps to ensure that a company's name and confidential project details will be blinded until publication.

- A-LIST will not conduct duplicative research, meaning that while surveys can be conducted on similar topic areas, the same (or essentially the same) questions will not be posed to the A-LIST participants in the same year, except for baselining purposes.
 - In the case of requests for duplicative research, A-LIST will take the following steps to advocate for a partnership, if appropriate. A-LIST will not identify the new company or the current research project sponsor at any point in this process until permission is received.
 1. A-LIST will advise the new company that it is unable to accept a new study on the same topic until the current study is completed, unless a partnering arrangement is put into place.
 2. A -LIST will share the Project Summary for a research project with the new company.
 3. If the new company wishes to pursue a partnering arrangement, A-LIST will reach out to the current sponsor of the research that is under investigation and ask whether there is a similar interest in collaboration. If the current sponsor is interested in collaborating with the new company, A LIST will obtain permission from both entities to disclose their respective identifies and will arrange for an introduction to take place.
 - If needed, A-LIST will develop detailed processes beyond these Operating Principles for exploring the potential for such partnerships, which will be approved by the AD PACE Executive Steering Committee.
- 8. The Operating Principles will be included as an Addendum to and incorporated in all contracts for A-LIST services.**
- 9. As A-LIST grows, these Operating Principles may be amended from time to time, with review and approval of the Executive Steering Committee of AD PACE.**