



AD PACE DATA COMMONS

OPERATING PRINCIPLES

UsAgainstAlzheimer's, (Provider) through its Alzheimer's Disease Patient and Caregiver initiative (AD PACE™), including its What Matters Most™ study series and A-LIST™ What Matters Most Insights Series (together, The What Matters Most™ Research Program,) has generated, received, collected and amassed a wide range of data, including insights, preferences, surveys, qualitative and quantitative research findings, all capturing perspectives of those affected by Alzheimer's (the "Data"). All such Data are housed in the AD PACE Data Commons (the "Data Commons").

These AD PACE Data Commons Operating Principles are provided as a guide for secondary analyses by any party (Receiver) who will be given the right to have access to and use of an identified subset of the Data in the AD PACE Data Commons pursuant to the terms of a Data Access and Use Agreement (Agreement) entered into with Provider. Such identified subset of Data will be responsive and relevant to Receivers' Research Project and Research Purposes. As used herein, the terms "**Research**" and "**Research Project**" refer to any work conducted within the Purpose (as defined in the Agreement).

The Operating Principles are intended to be included as an Addendum to and incorporated in the Agreement. To the extent any provision contained in these Operating Principles conflicts with the terms and conditions of the Agreement, the provisions of these Operating Principles will govern.

1. **Assurances regarding the DATA.** To Provider's actual knowledge:
 - a. All original research projects that have produced Data residing in the AD PACE Data Commons have been conducted in accordance with IRB approved protocols or such research has been exempted under federal regulation 45 CFR 46 and associated guidances. Such review provides, among other values, independent assurance that research projects are conducted with the highest levels of ethical compliance and protections for participant privacy and data security.
 - b. Experienced and qualified professionals have acted as Principal Investigators with supporting researchers.
 - c. All data delivered to the AD PACE Data Commons has been de-identified and managed with for participant privacy and data security.

2. **The Provider's decision to grant Receiver the right to undertake secondary analysis using an identified subset of the Data will be made taking multiple factors into consideration:**
 - a. Will the secondary analysis advance the interests of people living with the disease?
 - b. Will the information generated by the secondary analysis add to the base of knowledge being developed through the WMM Research Program?

- c. Will the secondary analysis build upon and advance the credibility of the AD PACE and the Provider?
 - d. Does undertaking the secondary analysis pose any risk to the reputation of Provider, AD PACE, the A-LIST, or the WMM Research Program, and has due diligence been undertaken to assure against any such risk?
3. **Goals for secondary research.** Receiver's general goals for its use of the Data will be explained to Provider in the Data Commons access request form. These goals will be held in confidence by Provider and will not be shared with sponsors of AD PACE, or otherwise, unless and until the information regarding the nature and or results of the Research Project are made public, as noted below.
5. **Results.** Results that emerge from the conduct of the Research Project will be made public in poster, manuscript form, or otherwise, not later than 12 months following completion of the analysis/secondary research and cleared by the applicable IRB as appropriate. Any exceptions to publication timing must be approved by Provider at project onset or at the time the sponsor of the secondary research first becomes aware that the 12-month publication requirement cannot be met. Further, Provider expects the sponsor of any secondary analysis to: (i) provide updates on the status of the Research Project during its course; and (ii) submit all analytical findings at its conclusion to the Provider to be shared in the Data Commons as provided below.
6. **Secondary analyses and associated research.** Receiver's Research Project will draw upon primary research conducted through the WMM Research Program and deposited in the AD PACE Data Commons and thus will be conducted leveraging already de-identified data placed in the Data Commons. The results of any additional associated primary or secondary research conducted by Receiver as part of the Research Project will also be de-identified. All such secondary analyses and associated primary or secondary research associated with the Research Project will be deposited in the AD PACE Data Commons within 12 months of the commencement of the Research Project, the termination of the Research Project, or upon publication, whichever shall first occur. Any exceptions to publication timing must be approved by Provider. 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. The intent is to build the AD PACE Data Commons as a growing and valuable research resource.
7. **Dissemination.** Some findings developed by Receiver may not be appropriate for publication but may be appropriate for dissemination in less formal ways (e.g., by Provider through the A-LIST's Pulse of the Community or through community blog post). Should Provider seek to disseminate such findings in a less formal manner in line with those described, Provider will afford Receiver the advance right to review and approve such communications, and Receiver will use best efforts to cooperate in assuring the accuracy and timeliness of such communications and in submitting the communications for IRB review, should this be required.

8. **Authorship.** Researchers associated with the original studies will be considered as co-authors on any publication of results from those projects, as appropriate, in accordance with ICMJE guidelines.
9. **Secondary analysis by an industry sponsor.** Provider recognizes the special need to achieve an appropriate balance of transparency and confidentiality when secondary analyses are being conducted by an industry sponsor. Accordingly,
 - a. 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.
 - b. The Project Summary will be used by Provider in public reports on its ongoing work and in discussions with other sponsors on new requests.
 - c. Provider will take reasonable steps to ensure that a company’s name and confidential project details will be blinded until publication.
 - d. Provider reserves the right to supplement, amend or develop additional processes beyond these Operating Principles to assure compliance with and potential engagement by the Recipient in the AD PACE initiative.
10. **Consequences for failure to comply with Agreement, including Operating Principles** (as determined in Provider’s sole discretion):
 - a. Revocation of license to the Data and Data Commons
 - b. No access to Data Commons until failure has been remedied

These Operating Principles may be amended from time to time by Provider.