![The Association for Frontotemporal Degeneration — FIND HELP·SHARE HOPE — AFTD logo]

AFTD – ALS Association Digital Assessment Tools for FTD and ALS Awards
INSTRUCTIONS FOR APPLICANTS

Before Getting Started

Review eligibility requirements: The principal investigator for the proposed project must verify their eligibility to apply for an award through this funding mechanism to access the full application. A detailed explanation of the eligibility criteria is provided below.

You are **eligible** to apply for a Digital Assessment Tools for FTD and ALS Award if:
- You have a faculty appointment at an academic institution, an equivalent position at a nonprofit research institution, or are employed by a for-profit organization (e.g., biotechnology company, digital technology company). Collaborative arrangements or partnerships (e.g., between academia and industry or between FTD and ALS researchers) are encouraged but one principal investigator for the team should submit the application.

AND

- You, another member(s) of the research team, or an external consultant/advisor have clinical and/or research expertise with both FTD and ALS.

AND

- Your proposed project will:
  - Advance the development of a specific digital tool with relevance for both FTD and ALS beyond the discovery or pilot stage
  - Develop a conceptual model inclusive of FTD and ALS as the foundation for future digital tool development
  - Advance harmonization of digital assessment tool data across FTD and ALS cohorts

AFTD welcomes applications from both U.S. and international investigators who meet these criteria. In addition, AFTD is committed to increasing the diversity of the scientific workforce and encourages applications by researchers from underrepresented or historically excluded populations.

You **cannot** apply for a Digital Assessment Tools for FTD and ALS award if:
- You are a postdoctoral fellow, postdoctoral research associate, or postdoctoral clinical fellow. Postdoctoral investigators can be included as a co-PI or other role on a research team headed by a PI who satisfies the eligibility criteria outlined above.
- Your proposed project is a discovery-stage or a first-in-human pilot study of a new digital tool.

- Your research team does not include anyone with clinical experience in <u>both</u> FTD and ALS. *This individual does not have to be the PI* – it can be a co-PI, a collaborator, or an external advisor. Please contact AFTD if you have any questions about whether your research team meets this requirement.

Completing your application

Step 1 – Create an account
All applications must be submitted through AFTD's online submission portal, which can be accessed [here](#) or on the AFTD website. If you are new to the portal, you will be prompted to enter your email address and select a password to create an account. If you are a return user, sign in using the email address and password you used previously to set up your account. If you have forgotten your password, follow the onscreen prompt to select a new password.

While Chrome is the preferred browser, the online submission portal supports the most recent versions of all major browsers.

Step 2 – Create or edit your profile
Enter all requested information in the relevant fields to create your portal profile. You will be able to edit this profile at any time – please update your information following any changes.

Step 3 – Complete the eligibility test
Answer all questions to confirm your eligibility. Once you receive a confirmation email, you will be able to access the body of the application. If you do not receive this email within 1 hour of submitting the eligibility test, check your spam folder; if you do not find the email there, contact AFTD for assistance (research@theaftd.org). Questions about eligibility determinations should be referred to the AFTD Director of Research and Grants (dniehoff@theaftd.org).

Step 4 – Complete the introductory questions
All projects involving human participants must obtain IRB approval. Approval of the IRB submission may be pending at the time you submit your application.

Step 5 – Complete and upload the Institutional Certification and Acceptance Form (academic applicants only)
Academic applications must be certified by the applicant's institution. Forward this form to the relevant individual in the grant administration or sponsored research office of your institution to complete and sign. Save in PDF format and upload where indicated.

Applicants at for-profit organizations do <u>not</u> need to complete this form.

Step 6 – Complete and upload the Description of Proposed Research
Upload a description of the proposed project where indicated. Please adhere to the following formatting specifications:
- Use an easy-to-read font, such as Arial (suggested), Calibri, Verdana, or Times New Roman

- Use a font size of 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.
- Single-spaced acceptable
- Margins must be at least ½ inch on all sides (i.e., top, bottom, left, right)

Your description should include:

- <u>Abstract (maximum 300 words)</u>: Summarize the aims and design of the project in language readily understood by a non-expert.
- <u>Research plan (maximum 10 pages)</u>: Include all of the following in the description of the research plan:
  - The rationale for the project and its relevance to both FTD and ALS
  - Background
  - Specific aims
  - Project plan and timeline
  - Experimental design and methods
  - Projects focused on the development of a conceptual model should clearly explain how the research plan will address specific recommendations outlined in the FDA Guidance "[Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments](#)."
- <u>Preliminary data (maximum 3 pages)</u>**:** For projects advancing development of a digital tool**,** summarize data confirming that the tool has undergone preliminary testing in healthy individuals and/or a clinical cohort. For projects focused on the development of a conceptual model, summarize evidence documenting the experience of persons with FTD and ALS or expert clinical input supporting the model.
- <u>Bibliography</u>: Include only the most relevant references. Citations should include the author names, title, book or journal, volume number, page numbers, and year of publication, however, a specific citation format is not required.
- <u>Data management and sharing plan (2 pages)</u>: AFTD supports the general principles of data stewardship outlined in the [NIH 2023 Data Management and Sharing Policy](#) and applicants are therefore asked to provide a concise Data Management and Sharing (DMS) plan that includes the following elements:
  - <u>Data type</u>
    Summarize the type and estimated amount of scientific data expected to be generated in the project
  - <u>Related tools, software, and/or code</u>
    Indicate whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, name(s) of the needed tool(s) and software, and specify how needed tools can be accessed.
  - <u>Standards</u>
    Describe what standards, if any, will be applied to the scientific data and associated metadata (i.e., data formats, data dictionaries, etc.).

- o Data preservation and access
  Give plans and timelines for data preservation and access, including the repository where scientific data and metadata will be archived and how the scientific data will be findable and identifiable
- o Access, distribution, or reuse considerations
- o *Describe any applicable factors affecting subsequent access, distribution, or reuse of scientific data (e.g., informed consent)*
- o Oversight of data management and sharing
  Indicate how compliance with the DMS Plan will be monitored and managed

The NIH has provided [samples of DMS plans](#) as well as a format template page you may helpful for writing your data management plan.

AFTD recognizes that some scientific data generated with an award to a for-profit recipient or a partnership between researchers in academia and a for-profit organization may be proprietary, or that the extent of data sharing may be constrained by restrictions imposed by licensing limitations or other terms. Applicants should provide justification for any such restrictions on data sharing. If you have questions or concerns about how data sharing expectations apply to for-profit organizations, please contact AFTD to discuss.

Save all elements of the Description of Proposed Research as a PDF file and upload where indicated.

- Additional files: Although not required, you may upload additional files in support of your application, such as
  - o Letters of support
  - o Guarantees from other investigators or vendors to provide necessary research materials
  - o Brief videos or other multimedia, if directly relevant to the proposed research (e.g., demonstration of a novel tool)

Step 7 – Complete and upload your budget
All budgets must be submitted using the budget template supplied in the submission portal.

Follow these guidelines in preparing your budget:
- The total budget request should be between $150,000 and $400,000. Budget requests exceeding $400,000 may be considered in exceptional situations and with sufficient justification; contact AFTD to discuss prior to submission.
- Up to 10% of the total budget can be allocated to indirect costs or institutional overhead.

Step 8 – Additional Sources of Research Support
List other ongoing and pending research support for the PI and any co-PIs, with a brief description of any potential overlap between these sources of funding and the proposed project.

Step 9 – Biosketches
Include a Biosketch for the PI and any co-PIs, utilizing the most recent [NIH format](#). You may use a biosketch prepared previously if it was created with this format. Save all biosketches as a single PDF file and upload where indicated.

Step 10 – Tool Development Plan
If your project focuses on advancing the development of a digital assessment tool, indicate whether you hold the rights to this tool. If another individual or organization holds these rights, describe any licensing or partnership agreements you have with the holder and how this might impact future development of the tool.

Follow the instructions in the application to provide additional information on your tool development plan.

Step 11– Business overview (for-profit applicants only)
For-profit applicants should provide an overview of their company to include the following:
- Company description and history
- Number of employees (full-time only)
- Financial statement (examples of acceptable documents include balance sheet, income statement, cash flow statement)

AFTD recognizes and respects the need for confidentiality in the review of proprietary information. All external reviewers are required to complete a written confidentiality and conflict of interest agreement with AFTD prior to serving on a review panel.

Step 10 – Review and submit your application
Prior to submitting your application, you will be able to save your work at any point and complete or edit the application at another time. You will also be able to remove files and upload new ones.

Please read your application carefully and make all final edits before submitting. Once you have submitted your application, you will be unable to make further changes.