APPLICATION INSTRUCTIONS FOR CORE RFPS

The ADDF's **Core Funding RFPs** require a two-stage process, which includes a Letter of Intent (LOI) and an invited Full Proposal. LOIs are accepted and reviewed on a rolling basis during four review cycles each year, corresponding to our four invited full proposal reviews. After reading our research priorities and the appropriate RFP, applicants can apply through our website.

The ADDF offers funding to researchers in both nonprofit and for-profit organizations. All nonprofits should apply through the Academic Application portal, and all for-profit companies through the Biotech Application portal.

SKIP TO: FULL PROPOSAL | BODY OF THE APPLICATION | REVIEWER EXPECTATIONS

LETTER OF INTENT (LOI)

To begin the application process, click to either submit an **Academic LOI** or a **Biotech LOI**. Complete each of the online sections below:

Log in or create a new account by selecting "New Applicant?" on the login page.

A principal investigator can only submit one LOI per review cycle. Accepted LOIs will remain active for two review cycles.

Project — Basic Information

Select the appropriate RFP and complete the required fields. **If this is a resubmission, you are required to submit a written point-by-point response to the reviewers' comments from the previous submission and upload as an attachment under "Response to Review."** If this is not a resubmission, you can skip those fields.

Principal Investigator's Contact Information

Please enter the information for the Principal Investigator (PI) who will be leading the project. In the case that there are more than one PI on the proposed project, please choose one administrative PI that would be the primary point of contact for ADDF. If invited to submit a full proposal, there will be places to indicate the key personnel involved with the project and their respective roles.

Project Details

The fill-in fields include:
• Scientific Rationals and Background (max. 500 words)
• Specific Aims (max. 300 words)
• Summary of Key Supporting Data (max. 300 words)

At any point, you may click on **Save & Finish Later** to leave the application website and return at a later point to continue editing. If you choose to do so, you will receive an automatic email reply from the system with the link to continue your application.

Once you have completed all of the sections, please click on **Save & Submit** at the bottom of the page. Once you have submitted your LOI, you will receive an automatic message indicating that "you have successfully submitted your proposal." Any changes or edits requested afterwards will need to be emailed to the Grants Team at grants@alzdiscovery.org.

LOIs are reviewed by ADDF's scientific staff to evaluate whether the stage of research and biological target is consistent with the ADDF's mission and funding priorities. LOI decisions will be sent within three weeks of submission, at the latest. Only invited full proposals will be accepted.

FULL PROPOSAL

Once you receive an email inviting you to submit a full proposal, log into your existing account and click on "Academic Application" or "Biotech Application" under **New** to begin the second stage of the application process.

Applicant Contact

You will be asked to review your Project Information, including request amount, project duration, and contact information. The PI should also complete a summary of their Biographical Information, and fill in Administrative Contact Information, if applicable.

Application

Complete the Executive Lay Summary, Scientific Abstract, Project Deliverables, and Summary of Key Supporting Data where indicated.

Please note that the Scientific Abstract, Specific Aims, and Summary of Key Supporting Data can be taken from what was originally submitted in the LOI. This is also the time to edit and/or expand on any of those fields, if needed.

Attachments

All other proposal information and materials, including the Body of the Application, will be uploaded here. Select the appropriate file type from the drop-down menu and upload all files.

A complete application will include the following materials:

- Body of the Application (*see Organizing the Body of the Application below for guidelines and requirements*)
- Compound Report Card* (*if applicable*)
- Preclinical Animal Study Worksheet* (*if applicable*)
- Work Plan Deliverables (*complete for each of year of requested funding*)
- Budget and Justification Form (*complete for each of year of requested funding*)
- Biographical Sketch Form (*existing biosketches in different formats are accepted*)

***** Please note that the Compound Report Card and Preclinical Animal Study Worksheet forms are downloaded in Excel format. Save the completed form as a PDF and to make sure that the text is not cut off. Additionally, when you "Save as PDF," please make sure to select "Fit to Paper Width" so that the columns remain on the same page and do not run off to the next page.

For Biotech applicants, the following are required:**

- Statement of Need
- Business Plan or Corporate Strategy – include company description and history, mission statement, market analysis, risk analysis, milestones, scientific and financial goals, and future plans
- Description of Management Structure – include a list of board members
- Capitalization Table
- Financial Statements – balance sheet, income statement, cash flow statement
- Company's Current Annual Budget
- Description of Investors to Date

- Intellectual Property Summary – note all IP linked to the project, including pending or granted IP, and if you expect to generate new IP; if the patent(s) are openly available online, please include the link(s) in lieu of attaching full files.

** If any of the materials are not available, please upload a page stating this.

Other Appendix Materials can include letters of support/collaboration, quotes from vendors or contract research organizations (CROs), or figures that cannot be embedded into the body of the application, but are directly relevant to the application and may be helpful to the review committee. Additionally, you may include unpublished manuscripts and IRB-ready clinical protocols. Publications and references that are openly available online should be linked in lieu of attaching the full files. All appendix files must be clearly labelled (i.e. "CRO quote 1," "Letter of Support 1," "Publication," "Clinical Protocol"). Please note that submissions are final and cannot be modified.

ORGANIZING THE BODY OF THE APPLICATION

This is the central part of the proposal and should contain the eight sub-sections listed below (indicate each section by number in the application). Sections 1-6 should not exceed 10 pages of written text, not including figures, other support, or references. **Please embed figures in the text if possible.** With embedded figures, your body of application may exceed 10 pages. Use at least 11pt. font and 1" margins.

Please refer to the **Reviewer Expectations** section below when completing each sub-section. Proposals will be evaluated on the following:

1. Novelty and Relevance

- Relevance to current ADDF funding priorities as outlined in the RFP.
- Novelty of the proposed project and its expected impact on drug discovery and development for Alzheimer's disease, related dementias, and/or cognitive aging.
- "Druggability" of the target or rationale in the context of the disease in humans. (Refer to the **Reviewer Expectations** section on Biological "Druggability" below).

2. Project Plan and Objectives

- Appropriateness and feasibility of the project plan and objectives – Include structured timelines and milestones for the project with clearly defined criteria for advancement of the project.

- Discussion should include potential pitfalls of the program with sufficient risk assessment and criteria to substantiate continuation of the program at each milestone.
- Project Objectives – Where appropriate, outline whether the goal is to develop a tool compound to validate a target or develop a clinical candidate. If developing a clinical candidate, the project plan should consider the desired clinical profile e.g. route of administration, length of treatment time, patient population, toxicity and safety.

3. Supporting Data

Strength and relevance of the supporting data (refer to the **Reviewer Expectations** section below)

4. Experimental Design and Methods

Appropriateness and feasibility of the methodology (refer to the **Reviewer Expectations**) – Provide study details including sample size, types of assays, experimental or clinical markers or outcomes, etc.

5. Description of Drug Discovery Team and Resources

Evaluation of the investigative team is not limited to the qualifications of the principal investigator and collaborators but is additionally evaluated with respect to the resources available to the applicant (refer to the **Reviewer Expectations**).

6. Intellectual Property (IP)

- Information on existing IP and stage of prosecution (e.g. use, composition of matter)
- If no IP currently exists, describe the projected plan to generate IP; note if you expect the project to generate new IP
- Indicate any freedom to operate issues
- Include a brief discussion on future directions and eventual path towards commercialization

7. Other Support

List other financial support, awarded and pending, and include grant title, principal investigator, percent effort of investigator, granting agency, amount, and projected funding period.

8. References

REVIEWER EXPECTATIONS

Full proposals will be reviewed by ADDF scientific staff and at least two members of our Scientific Review Board. The reviewers will evaluate proposals based on the guidelines and recommendations listed below. Please address, where relevant, the following issues within your proposal.

For Preclinical Studies

Biological "Druggability":

- Description of the target including any structural or computational biology known about the target (e.g. X-ray structure, binding site prediction, domain analysis, sequence comparisons).
- Systems biology analysis – Has the systems biology of the target been assessed? Is the target a node, or is there likely high possibility for redundancy?
- Availability of biological assays and description of duration and throughput – How do these assays translate in vivo, and in the context of the disease in humans?
- Potential mechanism-related side effects in animals and humans linked to modulating this target – What are the potential safety considerations due to likely off target activities or on peripheral targets?
- Related programs in the field; if any are known, please explain the advantages of your program.

Chemical "Druggability":

Please refer to and complete relevant sections of the Compound Report Card. Where appropriate within the proposal, include sufficient detail on:

- Chemical properties of the compound(s) to allow for assessment of "druggability" – All information provided is kept under strict confidentiality. All reviewers and ADDF staff are required to sign Confidentiality Disclosure Agreements (CDA).
- The starting point of compound/compound series description, e.g. natural compound, commercially available compound, virtual screen, proprietary drug like lead, existing FDA approved drug.
- Available compounds with similar mechanism of action – Where appropriate, it is recommended that comparison studies be included.
- Range of activity in primary, secondary and cellular assays.

***In vivo* Proof-of-Concept/Efficacy Studies:**

Please refer to ADDF's publication on best practices preclinical animal studies (Shineman et al., 2011). If applicable, fill out and include the Preclinical Animal Study Worksheet in your proposal.

- Justification for in vivo studies – Remember that hits are not drugs. The project plan or supporting data should include medicinal chemistry refinement, preliminary ADMET studies and PK/PD studies and/or dose

finding studies to justify moving into in vivo studies. A discussion or evidence for blood-brain barrier permeability, dose optimization, and details for expected route of administration should also be included.

- PK studies – While not required to be as comprehensive as IND-enabling studies, PK studies are required to demonstrate with enough confidence that the drug will reach the target at sufficient concentrations to mediate an effect.

For Clinical and Biomarker Studies

The ADDF typically provides funding for early phase clinical studies (phase o-IIa). Biomarkers should be included as the primary endpoint. Applicants are strongly advised to consider the following points during design of the study and preparation of the application:

- Clear justification for the proposed clinical study including discussion of supporting preclinical in vivo data.
- Clear definition of the control/placebo to be used and discussion regarding ethical considerations.
- Studies with patients or patient-derived material – The patient population should be clearly defined including detailed inclusion/exclusion criteria.
- Demonstration of power analysis to define numbers of patients or samples – Provide appropriate statistical reasoning to justify the proposed sample size and whether this will allow for adequate testing of the hypothesis.
- Recruitment issues – Include discussion that supports recruitment for the proposed trial. Investigators should be cognizant of recruitment difficulties in mild cognitive impairment (MCI) populations and provide evidence for ability to recruit the proposed patient population and number.
- Validation of biomarkers (within the literature or pilot studies) to detect changes in defined patient population within the specified treatment time of the proposed trial.
- Full IRB-ready protocol – Protocol for submission to the IRB should be included even if IRB approval has not yet been sought or awarded.
- Future plans for regulatory strategy and approval, where appropriate, i.e. feasibility of manufacture, intellectual property.
- Critical next experiments in order to advance the program to attract additional funding/licensing.

Team and Resources

Interdisciplinary teams across the fields of biology, medicinal chemistry, bioinformatics, pharmacology, toxicology, regulatory, intellectual property and clinical development are highly valued. The following will be considered when reviewing the investigative team and resources:

- Does the investigative team have access to the required expertise and resources required to conduct the study, e.g. if a compound modification/optimization plan is proposed, do sufficient medicinal chemistry and pharmacokinetics capabilities exist within the investigative team and/or related contractors to support the project?
- Has the applicant consulted with individuals with drug/clinical development expertise for the development of a commercialization plan? Where appropriate, have these individuals been consulted during design of the early preclinical studies?
- Where internal expertise is not available, has the applicant identified external partners e.g. consultants, contract research organizations (CROs) for execution of the experimental plan? (See ADDF ACCESS below).

SUBMIT ACADEMIC LOI | SUBMIT BIOTECH LOI

LOG INTO EXISTING APPLICATION

ADDITIONAL INFORMATION

ADDF ACCESS

The ADDF offers access to a network of consultants, research resources and CROs for ADDF investigators. For advice and support on selecting and working with a CRO during proposal development or for further information on resources available, please visit www.alzdiscovery.org/access.

Follow-On Funding

ADDF funded investigators that wish to apply for follow-on funding are encouraged to contact ADDF scientific staff **three months prior to the end of the funding period**. ADDF staff will schedule a conference call to discuss progress made towards the milestones and future plans for the program. Investigators will then be invited to submit a full application for follow-on funding through the standard application procedures.

Resubmissions

The ADDF accepts resubmissions if the applicant can adequately address the reviewer critiques. Applicants are required to attach a written point-by-point response to the review summary to the LOI. If the second resubmission is not funded, ADDF will NOT accept a third resubmission on the same project.

Please note the following costs are not covered:

- Indirect Costs/Overhead
- Capital Equipment
- Equipment Service Contracts
- Publication Costs
- Travel (unless travel is pre-approved under special circumstances)

On average, applicants are notified of decisions three months after full proposal submission. Please review proposal deadlines on our Funding Opportunities page.

Should you have any questions about the online application system or process, please contact the Grants and Contracts Team at grants@alzdiscovery.org.

Print

Alzheimer's Drug Discovery Foundation

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