CONDITIONS OF AWARD

HUMAN RESEARCH PARTICIPANT PROTECTIONS

The institution/organization that receives a grant from the Alzheimer's Association is accountable and has the primary responsibility for protecting the rights and welfare of individual human participants who consent to participate in investigations supported by these funds, including protected personal health information. Investigators may consult the Public Health Service (PHS) Grants Policy Statement, or Section 474(a) of the Public Health Service Act, implemented by 45 CFR Part 46 or The Office of Protection from Research Risks, National Institutes of Health, Bethesda, Maryland 20892 for additional guidance on the necessary safeguards for human research participants. Investigators may consult the Health Insurance Portability and Accountability Act of 1996 (HIPAA), implemented by 45 CFR 164.501 or the website of the U.S. Department of Health and Human Services (hhs.gov) or the appropriate equivalent in their federal regulations for additional guidance on necessary safeguards for protected personal health information. For non-U.S. organizations, these same guidelines are applicable, as well as local and federal entities that regulate human study participation.

Certification of ethical review - often referred to as Institutional Review Board (IRB) review in the U.S. - is not required at the time of submission of an application. Documentation is required at the time of award of the grant and on the anniversary date of the award (in conjunction with scientific and financial reporting). No more than 10% of the overall budget may be back-charged for costs incurred prior to obtaining ethical approvals for human participant research. Further, it is the awardee institution's responsibility to ensure appropriate ethical approvals for any subcontract of the institution as related to this funding.

Payment to begin work will not be issued without appropriate ethical approval, except in specific instances as specified by the Alzheimer's Association in the award letter. Additionally, for clinical trials, documentation of registration should be included with the ethical approvals.

This section applies only to awards where human research participants will be recruited.

ANIMAL WELFARE ASSURANCE

The Alzheimer's Association uses the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions. As stated in the PHS Grants Policy Statement, it "requires that applicant organizations establish and maintain appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities." It is the responsibility of institutions applying for a grant to the Alzheimer's Association to ensure the policies for the humane care and use of vertebrate animals are appropriately implemented. Investigators may contact The Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892, for further information. For non-U.S. organizations/ institutions, these same guidelines are applicable as well as local and/or federal guidelines in the location of the site(s).

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Animal welfare assurances for research using vertebrate animals are not required at the time of submission of an application. Documentation indicating appropriate ethical review approvals - often referred to as Institutional Animal Care and Use Committee (IACUC)- is required at the time of award of a grant and on the anniversary date of the award (in conjunction with scientific and financial reporting). Payment to begin work will not be issued without appropriate ethical approval.

This section applies only to awards where research animals will be used.

RECOMBINANT DNA APPROVAL

The Alzheimer's Association expects documentation from the Institutional Biosafety Committee rDNA Approval (or the equivalent at the institution/ organization) annually. It is the responsibility of institutions applying for a grant to the Alzheimer's Association to ensure that the policies for the use of recombinant DNA are appropriately implemented. Recombinant DNA (rDNA) review and approval is required at the time of award of a grant and on the anniversary date of the award (in conjunction with scientific and financial reporting). Payment to begin work will not be issued without rDNA approval.

This section applies only to awards where recombinant DNA technology will be used.

ALLOWABLE COSTS AND OWNERSHIP OF EQUIPMENT

Allowable costs are specified in the Program Announcement for each research mechanism. It is required that most of the funds awarded be used for the direct support of the research project in general, allowable costs include, but are not limited to:

- purchase and care of laboratory animals;
- small pieces of laboratory or clinical research equipment;
- special use computer hardware and software for neuropsychological or imaging studies;
- laboratory or clinical supplies;
- salary for the Principal Investigator;
- salary for scientific staff (including post-doctoral fellows and graduate students) and technical staff (including laboratory technicians and modest secretarial support);
- childcare costs provided by a licensed childcare provider – not to exceed $2,500 per budget period;
- open access publication fees for journal articles related to the funded research project;
- participant remuneration adhering to the NACC ADRC Best Practices located here: https://naccdata.org/adrc-resources/best-practices
- membership to ISTAART, the professional society of the Alzheimer's Association;
- Membership to scientific associations

- Professional development and communication training; and
- support for travel -- a total of $12,500 over a two-three year period not to exceed $7,000 per year. Please note that fellowship (clinical scientist and research) awardees are required to participate at least once during the award period in the Alzheimer's Association International Conference (AAIC); travel funds may be allocated to support registration and travel.

Costs not allowed include:

- Computer hardware or standard software (e.g. Microsoft Office, mouse monitor, computer parts)
- Laboratory equipment such as freezers, ultracentrifuges, RT-PCR, Microscopy/imaging equipment
- Service contract fees of equipment
- Construction or renovation costs
- Tuition
- Rent for laboratory/office space
- Visa costs and fees
- Expenses such as Data Network Recharges and Computing and communication device support services
- General liability insurances, such as GAEL
- Wire and currency exchange fees
- Salary and/or compensation for Alzheimer's Association Staff or current members of the Alzheimer's Association Medical and Scientific Advisory Group (MSAG) and the International Research Grant Program (IRGP) Council. A complete list of MSAG and IRGP Council members can be found on our website alz.org/grants.

Title for any approved equipment purchased by the organization with Alzheimer's Association grant funds belongs to the grantee organization.

Fellowship (clinical scientist and research) awards include stipends that **are not to be included** in the billable amount of the grant that is dedicated to research and associated costs.

IMPORTANT NOTE: The Alzheimer's Association reserves the right to disallow any expenditure(s) that are deemed unacceptable costs.

INDIRECT COSTS

Indirect costs are capped at 10 percent (rent for laboratory/office space is expected to be covered by indirect costs paid to the organization); **this is inclusive of indirect costs for the implementing institution as well as any subcontracts.**

ALZHEIMER'S ASSOCIATION INTELLECTUAL PROPERTY, LICENSING AND COMMERCIALIZATION

POLICY (INCLUDING DISTRIBUTION OF INCOME)

The Alzheimer's Association details the required distribution of net income derived from intellectual property and/or associated license or commercialization arising from research that was funded in part or in whole by an Alzheimer's Association grant in the attached Intellectual Property Policy, Licensing and Commercialization Policy of the Alzheimer's Association.

AWARDEE VOLUNTEER ACTIVITIES

The Alzheimer's Association depends on volunteers to support the scientific enterprise, including the International Research Grant Program. The Association assumes you will want to repay those volunteers by: remaining an active reviewer in our system; connecting to the Alzheimer's Association in your community (as applicable); and by responding to the Association's requests to engage in additional outreach.

RECRUITMENT FOR CLINICAL STUDIES REQUIREMENTS

Research projects funded by the Alzheimer's Association involving human subjects must address the appropriate inclusion or exclusion of individuals in the proposed research project. The Alzheimer's Association expects that recruitment efforts aim to represent the community in which the study is planned or being conducted in. Prior to distribution of funding (most likely having occurred during the application stage), the researcher must provide a description of their recruitment plan in the online reporting tool within Proposal Central; including an outline describing how their recruitment efforts will ensure diversity in their participants. Recruitment efforts should focus on representation of the community within key target groups, including but not limited to: sex, gender identity, sexual orientation, socioeconomic status, race, and ethnicity. The recruitment plan must provide a rationale for selecting the specific population justified in the context of the scientific question being proposed. If individuals from these key groups will be excluded, the researcher must provide an acceptable justification for the exclusion. Recruitment efforts will be tracked throughout the course of the grant and failure to track and report these efforts or failure to meet recruitment goals may impact subsequent payments. The Alzheimer's Association must be immediately notified of any changes to an approved recruitment plan for review and approval.

In studies that do not adequately enroll representative populations, the Alzheimer's Association reserves the right to terminate the award minus any previously committed funds.

This section applies only to awards where human research participants will be recruited.

INTERIM SCIENTIFIC AND FINANCIAL REPORTS

The Alzheimer's Association requires the awardee institution, with the investigator of record, to submit annual scientific and financial progress reports for the receipt of continued funding for multi-year grants. The interim scientific and financial reports are due on the anniversary date of the award and must be signed by the responsible business official of the grantee institution.

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Both reports must be submitted **ELECTRONICALLY.** Paper submissions will **NOT** be accepted. In some cases a hard copy of the financial report may be requested due to legibility. Financial reports should include only actual expenses to date. Expenses must be reported in U.S. Dollars. Failure to include expenses in U.S. Dollars will result in delays to approval and any future payments. The Alzheimer's Association reserves the right to ask for additional information pertaining to details included in these reports. Scientific reports should include progress to approved milestones, and are required to initiate subsequent payments. Human trials should provide evidence of trial registration updates every reporting period.

To download templates for the required reports, and to submit your annual reports; go to the same location that you used previously to submit your application:

https://ProposalCentral.com/login.asp

A tutorial for the submission of annual reports as well as other capabilities of the online system for grantees is available at the login page. Scroll down to the tutorial called "Grantee Instructions to access award information" or use the following link in your web browser to download the tutorial directly:

https://proposalcentral.com/docs/Instructions_Award_Info.pdf?version=2017.10.0.619

Follow the instructions in the tutorial to download the REQUIRED scientific progress report and financial report forms to be used for the submission of your annual reports and to attach the completed documents prior to the deadlines listed in your award.

IMPORTANT NOTE: Delinquent reports may cause funding to be delayed or terminated. Reports must be submitted by the requested due date.

IMPORTANT NOTE: For awards with multiple payments, subsequent payments will be released when funds are spent below USD $10,000.

FINAL SCIENTIFIC AND FINANCIAL REPORTS

Awardee institutions, with the investigator of record, are required to submit final scientific and financial reports on all research grants funded by the Alzheimer's Association. The responsible business official for the institution must sign all final financial reports. Final scientific and financial reports must be submitted **ELECTRONICALLY** within 90 days of the end of the award. Financial report should include only actual expenses in U.S. Dollars; estimated expenses are not allowed. Failure to include expenses in U.S. Dollars will result in delays to approval and any future payments Paper submissions will **NOT** be accepted. In some cases a hard copy of the financial report may be requested due to legibility. The Alzheimer's Association reserves the right to ask for additional information pertaining to details included in these reports. Human trials should provide evidence of trial registration closure at the final reporting period.

To download templates for the required reports, and to submit your annual reports; go to the same location that you used previously to submit your application:

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https://ProposalCentral.com /login.asp

A tutorial for the submission of annual reports as well as other capabilities of the online system for grantees is available at the login page. Scroll down to the tutorial called "Grantee Instructions to access award information" or use the following link in your web browser to download the tutorial directly:

https://proposalcentral.com/docs/Instructions_Award_Info.pdf?version=2017.10.0.619

Follow the instructions in the tutorial to download the REQUIRED scientific progress report and financial report forms to be used for the submission of your annual reports and to attach the completed documents prior to the deadlines listed in your award.

IMPORTANT NOTE: Final Progress Reports must be submitted by the requested due date. Delinquent reports will prevent future submission of the Letter of Intent (LOI) for consideration of possible funding.

IMPORTANT NOTE: Upon completion of projects, the Association encourages grantees to consider submitting an article describing results to *Alzheimer's & Dementia: The Journal of the Alzheimer's Association* or its two companion journals: *Translational Research & Clinical Interventions (TRCI)* or *Diagnosis, Assessment & Disease Monitoring (DADM)*. All three journals are open access. Note, payments of open access publication fees are eligible grant expenses and not limited to these two OA journals. For submission information, visit https://authorservices.wiley.com/author-resources/index.html.

IMPORTANT NOTE: At the end of the grant period, unspent funds greater than $75.00 must be returned to the Alzheimer's Association.

ANNUAL MENTOR EVALUATION

Fellowship (clinical Science and research) grants require the mentor to provide annual evaluations of the applicant's progress towards benchmarks for the duration of the award. This section applies only to the above mentioned awards.

REQUIRED benchmarks:

- Attendance at an Association-sponsored event for new investigators at the Alzheimer's Association's International Conference (AAIC)
- Acceptance of an abstract at AAIC
- Mandatory documentation of hours spent on face-to-face mentoring
- Citation of specific exercises of mentorship such as supervision of manuscript writing and submission or grant writing and submission
- Supervision of grant application reviews (not limited to the Alzheimer's Association review process but reviewing for other granting mechanisms are encouraged if possible; Alzheimer's

Association staff will coordinate supervised reviews for the Association)
- Specific instances of the facilitation of networking, introductions to colleagues and/or inclusion in discussions at scientific meetings
- Submission of funding proposal(s) to other funding agencies, including Alzheimer's Association, National Institutes of Health or National Science Foundation, Medical Research Council (UK), Canadian Institutes of Health Research, etc.

COMMUNICATION WITH RESEARCH PARTICIPANTS FOR CLINICAL STUDIES

Research results from clinical studies should be shared with research participants when possible, and in a timely manner. Results from studies that end prematurely should also be shared with research participants. The Participant Follow-Up Improvement in Research Studies and Trials (Participant FIRST) Work Group provides 17 recommendations (https://doi.org/10.1002/alz.12732) for achieving this, listed in the table below. We encourage all clinical studies funded by the Alzheimer's Association to incorporate these recommendations into the research and data sharing plan.

Pre-trial	1. Sponsors and funders should provide resources and funding in the study budget to ensure orderly trial close-out.
	2. Sponsors or principal investigators should ensure that the communication plan developed for the trial addresses the possibility of early stoppage.
	3. Study personnel must address the possibility of early stoppage during the informed consent process.
	4. General information about early stoppage should be available to members of the public.
	5. Study personnel should encourage participants and study partners to build and sustain their support networks.
Mid-trial	6. Study personnel should regularly check and update contact information for participants and study partners.
	7. Study personnel should remind participants and study partners that clinical trials might end early.
	8. Sponsors and principal investigators should anticipate and proactively address participants and study partners' questions and concerns when there is news from related clinical trials.
Post-trial	9. If a sponsor announces early stoppage via a press release, that press release should explicitly address participants and study partners.
	10. The sponsor or principal investigator should communicate news of early stoppage to site investigators and study personnel.
	11. Upon learning of early stoppage, study sites should initially contact participants via e-mail as soon as possible.
	12. As soon as possible after the initial notification e-mail is sent, study personnel should call participants and study partners and personally inform them that the trial has stopped.
	13. Sponsors, principal investigators, and study sites should consider leveraging social media to disseminate consistent information about early stoppage to participants and study partners.
	14. Sponsors and principal investigators should collaborate with patient advocacy organizations to support

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	participants and study partners when trials end early.
	15. Sponsors should prepare answers to FAQs and disseminate them broadly.
	16. Site investigators should invite participants and study partners to a personalized close-out meeting to cover information like participant arm assignment.
	17. Sponsors or principal investigators and sites should collaborate to ensure top-line results are shared with participants and study partners.

This section applies only to awards where human research participants will be recruited.

DATA SHARING

The Alzheimer's Association is committed to data sharing for Alzheimer's Association International Research Grant Program grantees. Data sharing is a necessary means to advance Alzheimer research results into systemic knowledge, usable products, and research procedures, leading to the overall improvement of human health. Clinical trials funded by the Alzheimer's Association are required to be registered in an appropriate clinical trial registry as part of the first reporting period. Appropriate registries can be found here: https://www.who.int/clinical-trials-registry-platform/network/primary-registries. The trial ID must be included in all publications resulting from the funded research.

The Alzheimer's Association requires the timely release and the sharing of final research data and other research resources generated from Alzheimer's Association funded research studies be shared and administered in accordance with this policy. Examples included in the "final research data" are the data, samples, physical conditions and other supporting materials created or gathered during the course of the work. The following principles should be followed:

- share data, tools, and results at the time of an associated publication, or the end of grant period, whichever comes first;
- make useful datasets and supporting information available to the broader research community at the time of an associated publication, or the end of grant period, whichever comes first, through data sharing platforms and repositories, noting that not all experimental datasets are useful at early or intermediate stages of generation, exceptions may be made on a case-by-case basis if the Association and research team agree that the data are not yet ready to be shared;
- use a streamlined data access process to allow high-throughput management of data access request approvals; make novel tools and research reagents (including, but not limited to, research models, cell lines, plasmids, viral vectors, antibodies, analysis methods, etc.) available as quickly as possible to academic and industry researchers either directly, or preferably through an appropriate and accessible distribution platform (e.g. Jackson Laboratory, Addgene, GitHub, or those recommended by the NIH here: https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data) with minimal costs and restrictions;
- whenever possible, avoid use of reagents, tools, samples, or data that cannot be easily shared;

- rapidly bring research findings and results to the research community through presentations at meetings and open access publication (e.g. preprint servers, open access journals, or making papers available on the investigator's website).

For clinical data, the rights and privacy of people who participate in Alzheimer's Association – sponsored research must be protected at all times. When applicable, data collected during these studies and shared for broader use should be free of identifiers and variables related to individual subjects. In addition, clinical awardees should take intentional steps toward better communicating with and supporting participants and their study partners throughout the clinical trial process, particularly when clinical trials end earlier than expected.

The Alzheimer's Association provides the Global Alzheimer's Association Interactive Network (GAAIN) as a resource to link all data generated as a result of this funding (see below for exemption) to be available for sharing. GAAIN – located at gaain.org – is a cloud-based, grid network infrastructure spanning centralized computational facilities in North America and Europe. The Alzheimer's Association recognizes there may be difficulties, limitations or other potential complications regarding an individual's or an institution's ability to comply with the Alzheimer's Association's data sharing policy as a result of institutional policies; local, state and federal laws and regulations, including the Privacy Rule; or local IRB regulations. When data sharing may be limited, applicants must explain such limitations to the Alzheimer's Association at the time of application for grants.

For non-clinical (i.e. animal related studies testing/ evaluating potential therapeutics in these models), the Alzheimer's Association expects researchers to submit their data within 12 months of the conclusion of their project to the AlzPED database, hosted by the National Institute on Aging/NIH. To submit data through AlzPED, awardees are expected to establish an account at https://alzped.nia.nih.gov/node/add/alzped-study and provide documentation of their data being submitted to the appropriate tool. AlzPED provides transgenic model and cross-transgenic model information across relevant translational criteria data sets such as therapeutic agents, and targets. AlzPED is designed to feature published and unpublished reports and to help identify the critical data, design elements and methodology missing from studies in order to increase transparent reporting, reproducibility and translatability of animal model efficacy testing studies. Following submission of data to AlzPED, researchers will receive a citable d.o.i (digital object identifier); investigators are expected to include the AlzPED d.o.i. in their final progress report.

In addition, awardees must identify potential impediments to data sharing with their Association contact at the time they negotiate grant agreement to accept the Alzheimer's Association grant award.

IMPORTANT NOTE: Failure to comply with the Alzheimer's Association Data Sharing Policy will result in ineligibility of the investigator for future funding from the Alzheimer's Association.

PUBLIC ACCESS POLICY

The Alzheimer's Association funds biomedical research related to Alzheimer's and other related

dementias. The main output of this research is new knowledge. To ensure this knowledge can be accessed, read, applied, and built upon in fulfillment of our goals, the Alzheimer's Association expects its researchers to publish their findings in peer-reviewed journals.

Awardees are required to publish open access manuscripts, to ensure the knowledge gained through this funded research is available to the entire research community. Note, payments of open access publication fees are eligible grant expenses.

In addition, it is a condition of funding from the Alzheimer's Association that all peer-reviewed articles supported in whole or in part by its grants must be made available in the PubMed Central online archive. This should happen in accordance with the following conditions:

- Authors are to deposit an electronic copy of their final peer-reviewed manuscripts in PubMed Central immediately upon acceptance for journal publication. It is the responsibility of the awardee to ensure journal articles are deposited into PubMed Central and that all necessary rights are retained in order to do so. Instructions for depositing manuscripts are available on the PubMed Central website (https://pmc.ncbi.nlm.nih.gov/about/submission-methods/).

- The manuscript is to be made publicly available without embargo in PubMed Central upon the Official Date of Publication. This requirement applies to all Alzheimer's Association grants awarded.

PubMed Central is a database of full-text biomedical journal articles available online without a fee. It is hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated within the context of other research findings, making it easier for scientists worldwide to pursue Alzheimer's and other related dementia research. Equally important, families, clinicians, patients, educators, funders, and students reap the benefits of information arising from funding by accessing publications on PubMed Central at no charge.

An author must acknowledge the support from the Alzheimer's Association's in every article arising from such funding. The acknowledgement statement must include the applicable Alzheimer's Association grant number. This will enable the Association to link the published outputs of research to the support it has provided.

All scientific progress reports must include the PMC ID number to publications in PubMed Central supported by the Alzheimer's Association.

In addition, data related to manuscripts should also be publicly shared, as outlined in the Data Sharing section within this document. Awardee research teams are expected to report on these activities as part of their annual reporting.

IMPORTANT NOTE: Failure to comply with the Alzheimer's Association Public Access Policy will result in ineligibility of the investigator for future funding from the Alzheimer's Association.

NOTIFICATION OF PUBLICATIONS

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One electronic copy of manuscripts and meeting abstracts reporting research acknowledging funds from the Alzheimer's Association must be submitted **ELECTRONICALLY** at the time of publication. These submissions must be shared with the Alzheimer's Association electronically using the same system outlined above for report submissions.

The Association will provide publicity assistance when the Principal Investigator notifies the staff prior to the release of findings in any scientific journal or major meeting presentations and will work with the Public Relations Officer of the institution to ensure coordination of efforts. Please contact the Communications Division, Media Relations Department at 312-335-5776 as early as possible in the process, for instance as soon as the manuscript is accepted for publication or presentation.

An acknowledgment of support provided by the Association must be included in any responses to or interviews with radio, television or print journalists when an Association funded grant is discussed.

ACKNOWLEDGEMENT OF FUNDING SOURCE

An acknowledgment of support provided by the Alzheimer's Association must appear in (i) scientific or academic publications of any material and (ii) conference presentations of any materials, whether copyrighted or not, if the data is based on or developed under Association-supported grants. The following wording should be used: This work was supported by a grant from the Alzheimer's Association (**GRANT ID**).

No such acknowledgment shall otherwise be made in connection with any publication, presentation or activity, including, but not limited to, postings on a website, without the prior written consent of the Alzheimer's Association, which it may grant in its discretion.

RIGHT TO AUDIT

In accordance with generally accepted accounting principles, the grantee institution ("Grantee") shall maintain reasonably full and complete records of the cost and completion of services performed under this Grant Award and the Conditions of Award Agreement (together, "Agreements"). During the term of the funding agreement with the Alzheimer's Association, and for a period of two years after their termination or completion, the Alzheimer's Association reserves the right to inquire and/or audit the Grantee's records as they pertain to the performance of the Agreements at Grantee's office. Upon fifteen business days written notice from the Alzheimer's Association, Grantee agrees to make available all records related to the funding award for inspection or audit at its offices during normal business hours as mutually agreed by the organizations (Monday through Friday, 8 a.m. - 5 p.m. local time).

RESTRICTIONS ON FUTURE FUNDING ELIGIBILITY

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Investigators should be in good standing with all reporting requirements for all of their prior Alzheimer's Association funding. Similarly for investigators who serve as principal investigators on clinical trials or studies should be in good standing with their reporting to any prior funding organizations as well as with the applicable registration site.

This policy will be strictly adhered to, no exceptions.

REQUESTS FOR ADMINISTRATIVE ACTIONS

Submit requests for administrative actions electronically through the proposalCENTRAL online system used for Interim and Final report submissions (described above). *When the request has been uploaded, please advise grantsapp@alz.org*

IMPORTANT NOTE: ALL letters and reports must be submitted electronically (see instructions above in reporting requirements).

Requests for administrative actions (e.g. re-budgeting, carry-over of unexpended funds, replacement of Principal Investigator, transfer of institution, overlap, extension of award, administrative supplements) **must be submitted electronically via letter,** which has been signed by the Principal Investigator of the application or grant and the responsible, bonded business official of the institution. Requests must be submitted 45 days prior to the desired date of action, signed by the grants office or the authorized signatory of the institution/ organization. Association staff will review draft letters for content and appropriateness prior to submission of the final signed request. The preliminary review does not indicate advance approval of the request; rather the preliminary review will ensure that all necessary information has been included.

Review and approval of requests for administrative actions is the responsibility of the staff of the Alzheimer's Association.

Re-budgeting

Requests for re-budgeting of more than 10% of the total awarded amount (direct + indirect costs) for that year **must be submitted electronically** for prior approval to the Alzheimer's Association. Requests to re- budget must be clearly explained and justified against the timely achievement of the specific aims of the grant. If possible, re-budgeting requests should be submitted with the interim/non-competing continuation report. If necessary, re-budgeting requests will be accepted mid-grant year.

Official re-budget requests should be submitted electronically. The request should be on institutional letterhead, and include a justification, the amount of funds being moved, the line item(s) funds will be taken from, and the line item(s) funds will be moved to. The request letter should be signed by the institutional representative and the PI.

Carryover of Unexpended Funds

No action is needed to carry forward unexpended balances into the future funding years. However, if this requires adjustment in budgeting and/or project timeline (i.e. possibility of no cost extension), the Alzheimer's Association should be consulted. An unexpended balance must be below $10,000 before the next payment will be released.

Replacement of the Principal Investigator

For most programs (exceptions named below), the request to replace a Principal Investigator **must be submitted electronically (see instructions above in reporting requirements)** by the appropriate faculty member (usually the Department Chair or Dean) and countersigned by the responsible business official of the grantee institution. The letter requesting replacement of the Principal Investigator must contain a curriculum vita of the proposed replacement Principal Investigator. Approval of a replacement Principal Investigator is the responsibility of the Association and subject to review by staff; the Association reserves the right to terminate a grant if replacement Principal Investigator is not approved.

Fellowship grants are awarded to support a particular Fellow and that grant is expected to transfer with the Fellow. These fellowship grants are awarded based on evaluation of the specific Fellow including their qualifications, their mentorship plan, and the research being proposed; therefore, requests to replace the Fellow are strongly discouraged and will likely not be allowed. Only in extreme circumstances will a Fellowship grant be allowed to transfer to a new PI, including the Fellow's mentor. ***Please note that a Fellow that transfers to an industry or other non-academic position does not qualify as an extreme circumstance.***

For Strategic Grants (SG) and Zenith, the grantee institution may request the replacement of a Principal Investigator. The request **must be submitted electronically (see instructions above in reporting requirements).** If the Principal Investigator of a Zenith or Strategic Grant (SG) award leaves research work for some reason, the Alzheimer's Association reserves the right to terminate the grant and the remaining funds minus non-cancellable obligations/fees must be returned to the Alzheimer's Association.

IMPORTANT NOTE: Principal Investigator's must maintain full-time employment at the grantee institution throughout the grant period. If the Principal Investigator loses full-time employment status at any time the award must be transferred to a new Principal Investigator. It is the responsibility of the grantee institution to notify the Association of any employment changes to the Principal Investigator within 30 days of the change.

Transfer of Institution

The Association will review requests to transfer a grant to another institution when the Principal Investigator moves during the award period. The key points in determining if a request to transfer will be approved are (1) if the resources and technical personnel at the new institution will adequately support the research through the remaining period of the award and (2) if both institutions and the Principal Investigator agree about the appropriateness of the transfer. The Alzheimer's Association reserves the right to approve the transfer or to terminate the funded

grant.

For transfers requested for fellowship (clinical science and research) grant awards, these programs are made, in part, as a result of the specific investigator and to support their training. The Alzheimer's Association expects these grants to follow the investigator to their new institution as applicable.

If approved, to transfer a grant to a new institution, the following documents are required:

- A release letter from the current institution;
- An Acceptance letter from the new institution stating their new position and the resources available to support the Alzheimer's Association funded research;
- A scientific and financial report detailing accomplishments to the date of transfer;
- Transfer all unexpended funds, minus non-cancellable obligations/fees; this must be paid back to the Alzheimer's Association, who will in turn, make a payment of unexpended funds to the new institution.

The request to transfer a grant should be submitted electronically at least 60 days in advance of the planned move to ensure Association staff have adequate time to review the request and ask for and receive additional information should it be necessary. You may request a six-month extension to complete work proposed in the grant for time loss during your move to the new institution.

Overlap with other Funded Applications

Investigators must inform the Association of any overlap, or concern about possible overlap, with other non-Alzheimer's Association grants. Overlap is defined as "two or more grants under the name of the same Principal Investigator, which shares at least one specific aim"; in addition, overlap means that the budget line items for each funding mechanism are also shared. It is not necessary to provide information about applications that share specific aims with an Association grant. The concern about overlap arises only when an investigator has been notified that they will be awarded a grant by another organization and that application, soon to be awarded, shares specific aim(s) with a grant from the Association, has overlap of proposed resources, and/or may result in Intellectual Property that was funded in whole or in part by the Alzheimer's Association and another party.

Extension of Award

An extension of the term of a grant without funds (no-cost extension) or with funds remaining at the end of the grant period (extension with cost) may be approved **when requested electronically 45 days prior to the grant expiration**. Typically, requests range from six to twelve months however you are allowed a 6 month extension for each year of the award (e.g. a two year award will be eligible for 2 no-cost extensions, up to 6 months each whereas a three year award will be eligible for 3 no-cost extensions, up to 6 months each). The Principal Investigator and responsible business official must countersign the letter requesting the extension, whether the extension is with funds unexpended at the end of the grant period or at no cost.
Although requests may not be made for the sole purpose of spending remaining funds, you

may expend remaining funds during the no-cost extension period. The duration of the extension and the expected products/accomplishments must be detailed in the letter. An extension of term may only be requested to complete work proposed in the grants.

Absence from work

Awardees must notify the Alzheimer's Association of any absence (unplanned or due to medical reason) from the funded research project longer than 60 days. In certain extreme cases when the Awardee is unable to communicate with the Association due to illness or accident, the department chairperson and/or authorized personnel from the institution may submit the request on their behalf. The Award is subject to early termination unless the absence has been requested and authorized in advance by the Alzheimer's Association.

A written request should be submitted to Alzheimer's Association indicating the dates of the leave, the reasons for the request and the Principal Investigator's intention to resume their work on the funding project. The Alzheimer's Association will review the request and determine the most appropriate course of action.

Change of Names and Addresses

If an investigator moves while an application is under review by the Association, it is necessary to submit electronic notification of the new address and the date of the move by updating the PI profile in proposalCENTRAL. In some instances, great difficulty has been encountered trying to find an investigator to inform him/her of the award of a grant.

If the business official responsible for the grant or application at the institution is changed, the investigator and new business official should update information electronically in the proposalCENTRAL profile as soon as possible.
Prompt online notification through proposalCENTRAL, of changes in names, titles, addresses, phone and fax numbers, email addresses will help to avoid delays in processing any actions or requests.

Other Administrative Actions

For other administrative actions not covered in this document, the investigator should submit an electronic letter detailing the request and the rationale.

IMPORTANT NOTE: ALL letters and reports must be submitted electronically (see instructions above in reporting requirements).

Responsibility for Subcontractors

Grantee and Institution must ensure any permitted subcontractors comply with these conditions of award and are responsible for all acts and omissions of subcontractors undertaken pursuant to these conditions of award. Neither Grantee nor Institution may seek to count an indirect

subcontractor cost as a direct cost hereunder.

Termination of Grant Award

The Association and/or grantee institution may terminate the remainder of any Award granted, in whole or in part, pursuant to these conditions of award but not yet paid at any time by providing at least 120-day notice prior to January 1 of the year in which such termination will be effective.

Any award that does not submit an executed copy of this award letter and conditions of award within 12 months of receipt by the grantee institution, or interim or final scientific and financial reports within 12 months of their due date listed on proposalcentral will be considered abandoned, and the Association reserves the right to terminate.

FINANCIAL CONFLICT OF INTEREST

The Alzheimer's Association is committed to preserving the scientific community and general public that the research we support is conducted without bias and with the highest scientific and ethical standards. A financial conflict of interest may exist when the applicant has significant financial interest that could directly and significantly affect the design, conduct, or reporting of the funded research. The applicant shall disclose any significant financial interest that may affect the submission and if so, approval, of the research grant. The institution is responsible for appropriate monitoring and management of investigator-related financial conflict of interests. It is the responsibility of the awardee to let Alzheimer's Association aware of any changes to the Financial Conflict of Interest during the period of the award.

This policy will be strictly adhered to, no exceptions.

RESEARCH INTEGRITY

Research misconduct by a Grantee receiving Alzheimer Association support is contrary to the interests of Alzheimer's Association, the individuals and the families affected by Alzheimer's or another dementia, and the broader general public that it seeks to serve, as well as to the integrity of research, and to the conservation of donor funds. The Parties hereby agree to follow, and Institution shall cause Grantee and Sponsor to follow the Institution's policies as they relate to Research Misconduct and confirm that they are at least as rigorous as the policies by the NIH (Public Health Service Policies on Research Misconduct 42 CFR 93).

For the avoidance of doubt, the NIH defines "Research Misconduct" to mean fabrication, falsification, or plagiarism (further defined below) in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

a) Fabrication: Making up data or results and recording or reporting them.
b) Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the

research record.

c) Plagiarism: The appropriation of another person's ideas, processes, results or words without giving appropriate credit.

The Alzheimer's Association will investigate any allegation of misconduct with the award institution. Actions that the Association may take include a pause of the funded project pending the outcome of the investigation, return of funds if any research misconduct is identified, and possible implications for any future funding to the organization from the Association. Other actions may be identified based on the circumstances. To report allegations of research misconduct, please contact Heather Snyder, Ph.D. (hsnyder@alz.org).

NONDISCRIMINATION AND HARASSMENT STATEMENT AND PROCESS

Alzheimer's Association is committed to providing an environment free from harassment and discrimination. Alzheimer's Association strictly prohibits harassment and discrimination based on race; creed; color; religion; sex; sexual orientation; national origin; ancestry; age; veteran status; citizenship status; marital status; physical or mental disabilities; pregnancy, gender identity or expression (including transgender status); genetic information; and any other characteristic protected by federal, state or local law.

The Association takes any allegation of discrimination and harassment seriously and is committed to make sure research funded by the Alzheimer's Association is occurring in a safe environment. The award institution will review allegations of discrimination and harassment in accordance with its institutional policies and applicable laws and regulations. If institution makes a finding of discrimination and harassment regarding an individual participating on an Association funded award, then institution will, as permitted by policy and applicable law and regulation, provide Association with a summary of the outcome of that review. In the event Association brings an allegation to the attention of institution, institution will review and will make best efforts to keep Association apprised of the outcome of the review. The contact person for harassment and discrimination for Alzheimer's Association is Heather Snyder, Ph.D. (hsnyder@alz.org).

EXPORT CONTROLS

The Alzheimer's Association and U.S.-based Grantee Institutions acknowledge that they are subject to U.S. export control laws and regulations (collectively, "Export Control Laws"), which include (without limitation) the International Traffic in Arms Regulations (ITAR), the Export Administration Regulations (EAR), and regulations and orders administered by the Treasury Department's Office of Foreign Assets Control ("OFAC Regulations"). Each party agrees to comply with all Export Control Laws. Neither party shall disclose any technology or technical data subject to Export Control Laws unless and until a plan for the transfer, use, dissemination, and control of the information has been approved by each party's Export Control Officer.

COMPLIANCE WITH U.S. SANCTIONS AND ANTI-TERRORISM LAWS

The Alzheimer's Association requires that (i) the Grantee as well as all subcontractor and subgrantees, of the Grantee, comply with all applicable U.S. laws, regulations, rules and executive orders, including, but not limited to, those related to sanctions and anti-terrorism, including but not limited to, the USA Patriot Act of 2001 and Executive Order 13224 (collectively, the "Laws"), and (ii) use the grant funds in compliance with all applicable Laws.

To this end, Grantee understands and agrees that, if during the award period, a Grantee or any subcontract or collaborator Grantee becomes subject to U.S. sanctions, the Association will, in its sole discretion, take any and all action required to comply with such sanctions, including, but not limited to, termination of this grant award. Further, Grantee will not use and will not permit its subcontractors and subgrantees to use funds provided under this grant award, directly or indirectly, in support of activities (a) prohibited by U.S. laws related to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) with any countries or territories against which the U.S. now maintains or maintains in the future comprehensive or targeted sanctions (which, at a minimum, include Cuba, Iran, Syria, North Korea, and the Crimea Region and so-called Luhansk and Donetsk People's Republics of Ukraine), unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Association in its sole discretion. These prohibitions apply to the Association's funds that Grantee uses directly, as well as Association funds used by any of Grantee subcontractors and subgrantees.

Institutional Representative Initial that the terms stated on this page are accepted _____

INTELLECTUAL PROPERTY, LICENSING AND COMMERCIALIZATION POLICY OF THE ALZHEIMER'S ASSOCIATION®

The primary purpose of the Alzheimer's Association (the "Association") funding scientifically meritorious research is to advance its mission to eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. The Association recognizes that Intellectual Property (defined below) having public health, scientific, business, and/or commercial application or value may be made in the course of research supported by the Association. It is the desire of the Association that such Intellectual Property will be administered in such a manner that it is brought into public use at the earliest possible time. The Association recognizes that this may be best accomplished through obtaining Intellectual Property Rights (defined below) and the commercial licensing of such Intellectual Property Rights to third parties. The Association's Intellectual Property Policy as set forth herein applies to all Governed Intellectual Property Rights (defined below).

1. "Intellectual Property" means, individually and collectively, software, invention, technology, discovery, application, method, process, practice, procedure, conception, know-how, show-how, creation, idea, work, item, documentation, correspondence, manual, image, prototype, test version, sample, work flow, report, development, data, specification, design, product plan, research and development, customer list, and information of any kind, whether existing or perceived in paper, electronic, digital, pictorial, ephemeral, visual, audible, tangible or intangible form or format.

2. "Intellectual Property Rights" means each and all of the following, anywhere in the world and under any law: (i) patents (including utility, design, and other patents and utility models), patent applications (including Provisionals, continuations, continuations-in-part, divisionals, reissues, re-examinations, substitutions, and extensions), invention disclosures, and foreign and international equivalents thereof, and any right of priority related thereto; (ii) copyrights, and any application for registration and any registration of any copyright; (iii) mask work rights, and any application for registration and any registration of any mask work right; (iv) personality rights, and attribution, integrity, and other moral rights; (v) rights in or arising from trade secrets, data, databases, or confidential or proprietary Intellectual Property; (vi) trademarks; (vii) all other intellectual property rights of any kind; (viii) all applications and registrations for the foregoing; and (ix) all rights, claims, and remedies related to any past, present, and/or future infringement, misappropriation, and other violation of any of the foregoing rights.

3. "Governed Intellectual Property Rights" means any Intellectual Property Rights arising from research that was funded in whole or in part by the Association, including any research performed, supervised, or subcontracted for by the grantee institution during the term of the grant using any Association funds.

4. The grantee institution shall provide timely reports to the Medical & Scientific Relations Division of the Association providing a list of all Governed Intellectual Property Rights disclosed during that period. In no event shall the report be provided more than 60 days after the disclosure of an invention or the filing of an application for Governed Intellectual Property Rights. The list shall include

sufficient information for the general nature of the Governed Intellectual Property Rights to be understand including, but not limited to, the inventors' names, a brief description of the invention/technology/work, and any application filing information. Upon the Association's request, all documentation relating to the Governed Intellectual Property Rights shall be provided to the Association. The Association shall agree to maintain the confidentiality of such documentation by executing a confidentiality agreement mutually agreed to by the grantee institution /inventor and the Association.

5. The grantee institution shall be solely responsible for the pursuit and maintenance of the Governed Intellectual Property. All expenses associated with the pursuit and maintenance of Governed Intellectual Property Rights shall be borne by the grantee institution or individual awardee including but not limited to filing fees, attorney fees, issue fees, maintenance fees, and annuities. Other than with respect to permitted indirect costs (subject to the cap on indirect costs in the conditions of award), no Association funds may be used for the pursuit or maintenance of Governed Intellectual Property Rights without prior express written permission from the Association.

6. Subject to any specific written agreements otherwise, all right, title, and interest in and to the Governed Intellectual Property Rights shall belong to the grantee institution.

7. In the event that the grantee institution decides not to pursue an application, to abandon an application, or to cease to maintain a granted right relevant to Governed Intellectual Property Rights, the grantee institution shall notify the Association of this intent in a timely manner and the Association shall have the right to assume responsibility for the pursuit or maintenance of such rights at its sole expense. In such an event the grantee institution will transfer all right, title, and interest in and to the subject Governed Intellectual Property Rights to the Association.

8. Unless expressly waived in writing Association shall be entitled to an agreed share of any revenue derived from the commercialization, monetization (direct or indirect), licensing, and sale of the Governed Intellectual Property Rights including, but not limited to any profits, upfront or periodic payments, milestone payments, and royalty payments ("Revenue Share"). For clarity, funds received exclusively to provide support for on-going or future research are not subject to Revenue Share.

9. Except for those provisions outlined in clause 10, the agreed Revenue Share shall not exceed seven (7) times the Association Award. The Association shall have a superior right to Revenue Share payments over any other party that may be entitled to similar payments (i.e., the Association will receive the Revenue Share before any other party) except any parties whose contractual terms with the grantee institution pre-date the Association's. In the event that the grantee institution is offered a financial support arrangement that meets or exceeds the Association's Award and the preferential Revenue Share provisions of this policy threaten the likelihood that such an award will be granted, the Association agrees to negotiate in good faith with the grantee institution to identify a mutually agreeable position.

10. The grantee institution and the Association shall determine the Revenue Share by mutual agreement within 120 days after the filing of an application for Governed Intellectual Property Rights. In the event that the grantee institution fails to notify the Association of an application for Governed

Intellectual Property Rights within the terms of this Policy, the grantee institution and the Association shall mutually agree to a Revenue Share within 60 days after such notice is given and the Association may be entitled to up to eight (8) times the Association's Award (replacing the agreement in clause 9).

11. The grantee institution shall notify the Association within 45 business days of beginning any negotiation with a third party for the license, sale, or other transfer of right, title, or interest of the Governed Intellectual Property Rights, including any joint venture arrangements in which the grantee institution is a party. Any such agreements must bind the parties to those same Revenue Share provisions agreed by the Parties under clauses 9 and 10 herein. The Association does not need to be included in any third party agreement, but the grantee institution must adhere to the provisions of this agreement.

12. In the event that the grantee institution has not taken effective steps to bring a Governed Intellectual Property Right to practical application, either directly or through a license, within a reasonable time frame after such practical application is feasible, the grantee institution shall agree to allow the Association to assist in forwarding progress either through direct action or the identification of potential licensees.

13. If any Governed Intellectual Property is made with the joint support of the Association and any agency or department of the United States Government, the Association may defer to the patent policy of that agency or department upon written statement by the appropriate agency of government notifying the Association of its position with respect to the applicable Governed Intellectual Property.

14. If any Governed Intellectual Property is made with the joint support of the Association and some other organization, not an agency or department of the U.S. Government, that organization, the grantee institution, the inventor(s), and the Association will confer to arrive at a mutually satisfactory disposition of the Governed Intellectual Property rights.

Address all correspondence regarding this Award Letter to:

grantsagreements@alz.org
Alzheimer's Association®
Medical & Scientific Relations – Grant Operations
225 N. Michigan Avenue – 17th Floor

Institutional Representative Initial that the terms stated on this page are accepted _____