



August 5, 2022

Elise Gamertsfelder
The London School of Economics and Political Science

Re: Clinical trial transparency policy

Dear Ms. Gamertsfelder:

Thank you for sharing your ongoing study titled “Are Clinical Trial Registration and Reporting Policies of Public and Philanthropic Funders of Clinical Trials in the United States in Accordance with the WHO Joint Statement? – Protocol for a Cross-Sectional Study” and the ongoing work that you and your team are doing.

As you note in your protocol synopsis, the World Health Organization’s joint statement recommends that:

“Clinical trial registry records should be updated as necessary to include final enrolment numbers achieved, and the date of primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure). If clinical trials are terminated, their status should be updated to note the date of termination, and to report the numbers enrolled up to the date of termination.”

The Alzheimer’s Association monitors and evolves our reporting guidelines and expectations of all awarded research projects and their teams continuously. Based on the information included in the “Rating for the Alzheimer’s Association” that you provided, it is unclear what information the team has evaluated. We have over twenty different funding programs each year and only a few of these include clinical trials within their focus and areas of funding. The rating document refers to the ABA program or the “APO Biology in Alzheimer’s” grant program; this program has a focus on mechanisms of the underlying biology of APOE. The projects funded through this program are aimed at developing and/or evaluating model systems on the interactions of APOE biology. This is not a clinical trial mechanism.

For all of our grants, we have additional language (beyond the Request for Applications or RFA) that outline our processes and work with investigators that include our requirements to either (1) activate funding and/or (2) receive funding for initial or subsequent payments. These are communicated with the awardee following

notification of funding approval. Several of these steps are directly related to your queries and more details are outlined below.

These include:

- **Prospective trial registration:** The Association requires ethical approvals are in place before initial funding starts for any funding that will be used toward the recruitment and engagement of human participants in clinical studies. In addition, part of our start up discussion asks about trial registration such as in clinicaltrials.gov for studies that are at more than one site. This is part of their reporting to the Association.

Independently, we track these for review to confirm that funded Phase 1 or 2 studies for registration in clinicaltrials.gov and/or other entities. In the past, this has been part of the discussions however the most recently funded studies are required to include trial registration as part of the first milestone and it will be noted publicly in future requests for applications. This is to ensure compliance with this expectation.

In the last three years, we have 35 funded phase 1 or phase 2 studies through our dedicated funding program. Of those, 24 are registered in either clinicaltrials.gov or other appropriate entities. Nine (9) are working through contracting and/or do not yet have their ethical approvals (a requirement for our contracting). The remaining two (2) are being tracked and will be assessed at our next bi-annual follow up call to understand where registration is within their recruitment/start up activation.

- **Results published in journals:** The Alzheimer's Association includes in our Conditions of Award the following "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." Although this specific clause does not specify a timeline, we refer to the expectations of the CAP guidelines (Collaboration for Alzheimer's Prevention) which were co-authored by the Alzheimer's Association; these specify that not only should results be published but there is an expectation of data being shared more broadly than publication and specifies specific timeline expectations.

Additional language included in our Conditions of Award notes: "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. 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."

The Association also would consider other public sharing of information regarding the studies to be relevant; this can include sharing at scientific meetings. This last week, the Alzheimer's Association convened more than 10,000 scientists from around the world for the Alzheimer's Association International Conference (AAIC). AAIC is one of the scientific meeting platforms where funded awardees are expected to present information, including study design, ongoing progress and outcomes; others could include the American Academy of Neurology annual meeting, the AD/PD meeting or Clinical Trials in Alzheimer's Disease (CTAD) meeting. AAIC abstracts are published following the meeting in *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*. Presentations, as well as publications, of funded studies are tracked by staff and uploaded into the grant files of each of these awards. The Association does not specify a specific journal for publication, however, we do provide

public or open access publication fees as allowable costs.

- **Monitors trial registration and monitors results reporting:** Staff of the Association independently monitor and track trial registration as a part of the reporting and oversight of awards. As a part of the award letter and conditions, study teams are required to meet with the Association, based on specific milestones worked out between the study team and the Association after award approval, that include detailed timelines of when activities should be complete. Those milestone check in meetings are typically every six months.

Study teams provide detailed updates on the study progress, including any challenges and successes from the initiation of the study through its completion. This includes trial registration. Future payments are dependent on meeting study milestones and providing appropriate reporting. In addition, these discussions include detailed updates on the study progress where the study team shares information on the timelines of next steps and reporting, where and how reporting of results will be shared. These expectations are laid out in a kick off meeting prior to the initiation of the funding, including the study team and appropriate members of their administrative team.

In addition, the Alzheimer's Association provided a federated network for study teams to connect and link as a vehicle to reduce burden of sharing data and/or making data more discoverable. This tool - Global Alzheimer's Association Interactive Network (GAAIN) - is housed at the University of Southern California under the leadership of Dr. Arthur Toga. As part of the milestones bi-annual meetings, the study team is asked to share information about recruitment during the study, the progress and timeline while ongoing and sharing plans for data and results at the study conclusion. Further, regarding data sharing, it is also noted in our Conditions of Award: "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."

An additional note made in your evaluation is the lead investigator's past reporting adherence. The Association states in our Request for Applications as well as in our Conditions of Award for funded projects the following:

- The Alzheimer's Association does not accept new grant applications from currently funded investigators who are delinquent in submitting required reports and other deliverables on active grants. Investigators that have previous Alzheimer's Association awards closed as 'Incomplete' are not eligible to apply. This policy will be strictly adhered to with no exceptions.

Lastly, the Association's grants team has built a website to increase the ease with which all stakeholders can navigate and find all the relevant information for your needs.

As part of this redesigned site (alz.org/grants), the funding programs, expectations and requirements are being further built out to ensure policies and information relevant to our application process and award process are clear and available. As an organization, we are committed to transparency and there are several planned additions to make information that had been historically shared with study teams available for all to access at their convenience. These include:

- (1) Award activation steps, details and requirements, including requirements around ethical approvals and identified milestones.
- (2) Award documentation and conditions of award examples; these previously have only been shared on

request to an applicant and/or after an award has been approved.

To provide you with further details for your review, we have included an example of our Award Letter and our Conditions of Award to this letter; these are both immediately attached to this letter. These are examples of award documentation being used today for our most recently awarded projects, and as an organization we will continue our commitment to transparency and accountability.

Please let us know if you have any questions about this information.

Sincerely,

[REDACTED]

[REDACTED]

Vice President, Medical & Scientific Relations

CC:

[REDACTED], Chief Science Officer

[REDACTED], Vice President, Global Communications

[REDACTED], Director, News Media Engagement

March 25, 2022

PI, Degree

Institution

Address

City, State, Country, Zip

Re: [Name of grant program]

Dear Dr. Last Name:

The Alzheimer's Association is pleased to confirm that your application GRANT ID, "GRANT TITLE" has been approved for funding.

The grant will be funded beginning Month Day, Year.
The granting period is Month Day, Year to Month Day, Year.
The total amount of the grant is \$XXX,XXX.00 USD.

The award total (\$XXX,XXX.00 USD) is broken into bi-annual payments that are aligned with the milestone activities that are outlined and attached in Appendix A. Payments will be made following timely reporting (Teleconference Updates, Scientific Reports, and Financial Reports) as well as achieving milestones for each reporting period.

Reporting periods:

- Months 6, 18, 30: Teleconference with PowerPoint Update & Financial Report
- Months 12, 24, 36: Teleconference with PowerPoint Update, Written Scientific Report & Financial Report

Recruitment Efforts:

- Efforts to ensure that this trial is representative of the community in which the study is planned will be closely monitored throughout the duration of the grant
- Prior to distribution of funding, details outlining recruitment plan and efforts to ensure diversity in participants will be required and updates are a required component to each reporting period outlined above

Data Sharing Plan:

- Trial must be registered in an appropriate clinical trial registry as part of the first milestone
- Demographic data must be shared within 180 days of subject enrollment completion
- Timeline for sharing of rest of trial data must be provided & approved by Alzheimer's Association staff



The requirements for this grant are detailed in this Award Letter, which includes the Award Details, Financial Information Sheet, Conditions of Award, Patent Policy, and Appendix A as one document. The document must be signed, initialed where required by the institution/ organization authorized signature and the study's principle investigator and uploaded to your online file as a "pdf."

The Alzheimer's Association also **requires** the following **electronic files** to be uploaded to proposalCentral at: <https://ProposalCentral.com/login.asp>.

- Signed/initialed Award Letter, Conditions of Award and Patent Policy documentation as a "pdf"
- All ethical approvals that apply to the project

All of the above are required and must be **submitted electronically** to activate the award. ***Hard copies of the required documents will not be accepted.***

The Alzheimer's Association depends upon private support to invest in meritorious research projects. Therefore, your help and support are very important in the efforts to educate the general public and the scientific community about the disease and the Association. In accepting this research grant award, you agree to credit the Alzheimer's Association for providing funds for this research whenever you present the research or publish articles about the project. In addition, your acceptance allows the Alzheimer's Association to use your likeness in presenting your findings through press releases, interviews, or other activities such as hosting lay language abstracts on alz.org, and sharing Alzheimer's Association funding information to public databases (i.e. International Alzheimer's & Dementia Research Portfolio, IADRP). Please note the attached Conditions of Award for details of this commitment.

It is necessary for both you and a representative from the business office or Office of Sponsored Research from the **Institution**, to sign the form below. The signatures verify that the award is accepted by the **Institution** with the attendant requirements and that no part of this research project has been funded from another source. Also, complete the included form requesting the information for the business official that has fiscal responsibility for this award. ***Please retain a copy for your files and upload the complete Award Letter, Conditions of Award, and Patent Policy document to the pcCentral site.***

Thank you for your support of the Alzheimer's Association and commitment to research on Alzheimer's disease. If you have any questions, please contact grantsapp@alz.org.

Sincerely,

[ALZ Team]

cc: Name (Signing Official); Name (Financial Officer)

This **FY21** Research Grant is accepted on behalf of **Institution**. The requirements as specified in the Award Letter documentation are accepted. While it is acceptable for a project to have multiple funding sources, **no part of this application has overlapping funding from another source.**

The Alzheimer's Association depends on volunteers for its exemplary grant review process. Your grant could not have been funded without the hard work of those volunteers. The Association assumes you will want to repay those volunteers by remaining an active reviewer in our system by connecting to the Alzheimer's Association in your community (as applicable) and by responding to the Association's requests to engage in additional outreach



It is imperative that you respond when called upon to contribute to this support of the Alzheimer's and dementia research community.

By signing this document you are agreeing to all of the terms and conditions.

Institutional Official _____ Date _____
Signature

Print Name & Title (required)

Although not a party to this entire agreement, I have reviewed the Agreement and understand the provisions in the Agreement regarding the role of the Grantee for this Project.

Principal Investigator _____ Date _____

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. - and approval 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.

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).

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.

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.

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);
- open access publication fees for journal articles related to the funded research project;
- membership to ISTAART, the professional society of the Alzheimer's Association; and
- support for travel -- a total of \$5,000 over a two-three year period not to exceed \$2,500 per year (if you request the full \$2,500 for 2 years and are requesting a 3 year award you will not be able to request travel funds for one of those years). Please note that the AARG/AARG-D 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 and software for general office/word processing use;
- tuition costs for students;
- construction costs or renovation costs;
- rent costs;
- General liability insurances, such as GAEL and
- currency conversion costs for International Awards.

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

AACSF/D and AARF/D 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 POLICY (INCLUDING DISTRIBUTION OF INCOME)

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

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.

DIVERSE AND INCLUSIVE RECRUITMENT FOR CLINICAL STUDIES

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 diversity within key target groups, including a diverse representation of (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.

INTERIM SCIENTIFIC AND FINANCIAL REPORTS

The Alzheimer's Association requires 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. 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. 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.

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.

FINAL SCIENTIFIC AND FINANCIAL REPORTS

Investigators 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; estimated expenses are not allowed. 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.

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: 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.

ANNUAL MENTOR EVALUATION

Mentoring grants (AACSF, AACSF-D, AARF and AARF-D) require the mentor to provide annual evaluations of the applicant's progress towards benchmarks for the duration of the award.

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.

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.

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.

For clinical data, the rights and privacy of people who participate in Alzheimer's Association – sponsored

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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. Clinical trials funded by the Alzheimer's Association are required to be registered in an appropriate clinical trial registry as part of the first milestone.

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 gaaain.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.

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.

(<http://www.healthra.org/resources.publicaccess.html>)

- ☐ The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal 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.

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

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 publications of any material 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 an Alzheimer's Association**

Grant (**GRANT ID HERE**).

In addition, an acknowledgement of support provided by the Alzheimer's Association must appear in presentations of any material, if the data is based on or developed under Association-supported grants. Whenever the Principal Investigator is informed of sponsorship through the generosity of a donor, the specific grant name should be used. For example, the Alzheimer's Association/Samuel A. Blank Research Grant.

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

As of the posting of this policy, the Alzheimer's Association will not accept new research grant applications from investigators who are delinquent in submitting interim/final scientific or interim/final financial reports on current and/or previous grants or are in conflict with the conditions put forth in this document.

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

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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.

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 in the AACSF/D and AARF/D programs 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.

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 Principle 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 AACSF/D and AARF/D 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.

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 Sponsoring Institution shall cause Grantee and Sponsor to follow the Sponsoring 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

Institution and PI Initial that you accept the terms stated on this page _____

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).

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 open access journals: *Translational Research & Clinical Interventions (TRCI)* or *Diagnosis, Assessment & Disease Monitoring (DADM)*. 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>.

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 is Heather Snyder, Ph.D. (hsnyder@alz.org).

INTELLECTUAL PROPERTY 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 10 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.
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:

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