

Research Grant Process
Conflict of Interest Safeguards
November 2012

Summary Roles/Responsibilities for Research Grant Award Process

- 1. The Association's annual operating budget of total revenue and total expense is reviewed and recommended in the following sequence: Staff to the Finance Committee to the Executive Committee to the Board of Directors. The Board of Directors give final approval to the annual budget and any mid-year adjustments. The approval of the expense budget is a total amount; however, the anticipated allocation to research grants is specifically noted along with the allocations to other significant areas of Association operations.
- 2. Researchers submit grant applications for ADA funding.
- 3. The **Research Grant Review Committee** (RGRC) conducts a preliminary review and score of all grant applications. This review is performed remotely by RGRC members, providing written notes. Approximately 20-25% of the applications gualify for Final Review.
- 4. The RGRC holds an in-person meeting to conduct the Final Review of qualifying grant applications. The primary reviewer summarizes the proposal and discusses the application's strengths and weaknesses. After discussion among the assigned reviewers and the Committee-at-large, a final vote is taken. The scores for an application are averaged after the meeting to derive the final assessment (priority score) of the proposal.
- 5. Association staff ranks the applications in priority score order and prepares a preliminary assessment of which applications will be funded based on the available budget.
- 6. The funding assessment is reviewed with members of the **Research Policy Committee** (RPC) for feedback on whether the distribution of grants among the different award categories appears appropriate and for guidance on grants that may be just above or just below the funding line.
- 7. Staff make the final funding determination and send award notifications.

<u>Ad-Hoc Review</u> Grant applications may be solicited at times outside of the of scheduled RGRC review cycle or in areas that don't match appropriately to the RGRC's expertise. Examples include training awards and targeted awards. These grants follow a similar process through an ad-hoc review Committee.

Conflict of Interest (COI) Protections

The following protections are in place to manage potential COI in the grant award process. Compliance with these protections must be documented in the minutes of each applicable Committee/Board meeting. The Research Department is responsible to keep records of COI compliance for the Research Grant Review Committee and all ad-hoc review committees. In addition, COI protections must be followed if (a) an immediate family member of an applicable Committee/Board member may be affected or (b) a professional associate of a member of the RGRC, ad hoc review committee, or RPC may be affected. The terms *immediate family member* and *professional associate* are defined later in the document.

- 1. **Staff** and immediate family members are ineligible to receive Association research grant funding. Staff complete annual COI disclosure forms.
- 2. For the Finance Committee, Executive Committee and Board of Directors' review of the budget, research funding disclosures are provided. The disclosures indicate the total amount of Association research grants that are provided to Committee/Board members or their institutions, noting whether the Committee/Board member is a principal investigator. Committee and Board members complete an annual Conflict of Interest disclosure form.

During discussion, Committee/Board members may comment on the proposed research budget as it relates to the impact on the ADA grant program or the overall state of diabetes research. However, Committee/Board members may not comment on the potential impact to an individual, institution or specific project.

- 3. Protections for the Research Grant Review Committee are outlined in the following document "Conflict of Interest, Confidentiality, and Non-Disclosure Policy for Grant Application Reviewers."
- 4. Conflict of interest disclosures are reported prior to each **Research Policy Committee** meeting. The disclosures indicate which Committee members either have received individual ADA research grants or are employed at an institution that is the recipient of an ADA grant. All members must acknowledge the COI report at the beginning of the meeting.

When staff presents the preliminary funding assessment of grant applications and requests feedback/guidance, the information provided is limited to application title, score, dollar amount, and basic information in order to maintain anonymity of the grant applicants. RPC members who submitted a grant in the funding cycle under discussion must recuse themselves from providing any funding feedback or guidance.

RPC members must recuse themselves from any policy discussion and vote that have financial implications if the member's personal funding could be directly affected by those decisions (i.e., if the member is a current grant holder). Examples include: (1) Committee guidance on adjusting both existing and current award amounts to stay within the approved budget (2) Committee guidance on the selection of applications for funding.

Collaborative Research Projects

At times, the Association has the opportunity to collaboratively fund a grant with another organization. The Research Policy Committee has developed guidelines for acceptable collaboration projects. If a proposed project falls within the guidelines, staff may proceed with the collaboration, keeping the RPC informed and subject to available budget. If a proposed project falls outside of the guidelines, the project is presented to the RPC for approval. RPC members who could benefit financially must recuse themselves from discussion and vote.

Terms Defined

Immediate Family Member – spouse/domestic partner, sons, daughters, parents, brothers and sisters, and any person living in the same household as the individual

Professional Associate - colleague, collaborator, co-author, scientific mentor, or student with whom the reviewer/Committee member is currently conducting research or other professional activities, or with whom the reviewer/Committee member has personally worked within three years of the review date.



American Diabetes Association Research Program
Conflict of Interest, Confidentiality, and Non-Disclosure Policy for
Grant Application Reviewers
November 2012

CONFLICT OF INTEREST

A Conflict of Interest (COI) in scientific peer review exists when a reviewer has an interest in an application or a proposal that is likely to bias his or her review of it. A reviewer who has a real COI with an application or proposal may not participate in its review. Appearance of a COI should be avoided whenever possible.

Bases for COI

The following guidance will assist in determination of whether a real or apparent COI exists. The guidance is not all-inclusive, due to the nature of the COI subject matter. Therefore, American Diabetes Association Research Program staff should be consulted when there is any question about real or apparent COI.

There are several bases for a COI including employment, financial benefit, professional benefit, and personal or professional relationships. If applicable, any one may serve to disqualify a reviewer from participating in the review of an application or proposal.

Financial Benefit: A COI exists where a reviewer has received or could receive direct financial benefit of any amount, other than from employment, from an applicant institution or principal investigator related to the application or proposal under review.

Professional Benefit: Individuals contributing to an application/proposal in a professional capacity, and/or stand to benefit professionally should the proposal be funded, may have a COI. A professional role is defined as anyone who significantly contributes to the scientific development or execution of the project in a substantive measurable way, regardless of whether they are compensated for the contribution. Examples of major professional roles include Principal Investigator (PI), key personnel, contributor, consultant, collaborator, sponsor or mentor. Regardless of the level of professional involvement, if the individual feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue.

Multi-Site or Multi-Component Project: Persons serving as either the PI, as one of the key personnel, collaborator, or as a consultant on one component of a multi-site or multi-component project have a COI with all of the proposals connected with the same project; and, they may have a COI with other applications or proposals submitted by the principal investigator, other key personnel, collaborators or consultants of the same project.

Employment: A reviewer who is a salaried employee, whether full- or part-time, of the applicant institution, or who is negotiating with the organization for employment, shall generally be considered to have a COI with regard to applications/proposals from that organization. If a reviewer is employed at a multi-component institution, they are considered to have a COI with regard to applications/proposals from the same component, but not necessarily with applications/proposals from a separate component. For example, the distinct campuses of the University of California (UCSD, UCSB, UCD, UCSD, UCLA) are considered separate components of a multi-component institution, as are the separate affiliates of the Harvard system. Distinct academic departments within the same institution (Department of Biology and Department of Chemistry) are not considered separate components.



Relatives or Associates: A COI exists if a close relative or professional associate of a reviewer submits an application or proposal, or receives or could receive financial or professional benefits from, or provides financial or professional benefits to, an applicant. In such case, it will be treated as the reviewer's benefit. A close relative is defined as a parent, spouse/domestic partner, son, daughter, and any person living in the same household as the individual. A professional associate is defined as any colleague, collaborator, co-author, scientific mentor, or student with whom the reviewer is currently conducting research or other professional activities, or with whom the reviewer has personally worked within three years of the date of the review.

Longstanding Disagreements: A COI exists where a potential reviewer has had longstanding scientific or personal differences with an applicant.

Implications of COI

Depending on the specific COI, a reviewer may be differentially impacted in their ability to participate in the review process. For example, members of a review committee who have submitted a grant application/proposal may not participate in the grant review process during the time that their grant application/proposal is being considered. Other COI require that a reviewer not review an individual application, but do not prevent the reviewer from participating in the review process overall. The following table summarizes the consequences of specific COI situations for reviewers.

Conflict of Interest Summary for ADA RGRC and Ad hoc Review Committees		
Circumstances creating a COI such that the individual:	Circumstances creating a COI such that the individual:	Circumstances that do not create a COI, and therefore, the individual:
May Not Serve on RGRC	May Serve on RGRC, May Not Review or Participate in Discussion of Individual Applications	May Serve on RGRC, May Review Individual Applications
PI on grant application under review at RGRC	Employment (at same Component Institution)	Providing free resources
	Financial Benefit	Providing free services
	Professional Benefit	Collaborator of a collaborator
	Relatives and Associates	Data donations to a central repository
	Scientific Disagreements	Co-author of position paper, review article, professional group or conference report
	Collaborator (collaboration or joint original publication in the last 3 years)	Multicenter network not related to application

Responsibilities for Managing COI

American Diabetes Association Research Program staff is responsible for overseeing the management of COI (and appearance of COI) during the peer review process. ADA Research Program staff will:

- Provide written instructions to reviewers outlining applicable policies regarding COI.
- Manage questions regarding COI and appearance of COI by:
 - Association Research Program staff will determine whether a particular situation in question involves a COI and whether a reviewer may be involved in the review of the application(s) or proposal(s) in question.
 - Where there is an appearance of COI, but not sufficient grounds for disqualifying the reviewer, the American Diabetes Association Vice President of Research will determine whether the individual may participate in review. Research Program staff will document the circumstances and resolution of the apparent COI.
- Collect signed declarations from reviewers regarding COI prior to and following the review process.

All Research Grant Review Committee (RGRC) members and ad hoc review committee members are personally responsible for reporting any potential COI (and appearances of COI) during the review process. All members, including ad hoc reviewers and reviewers who only provide written reviews (and do not attend a live review meeting) must:

- Bring to the attention of the American Diabetes Association Research Program staff any potential COI that may pertain, whether real or apparent;
- Certify that they have identified all COI to ADA Research Program staff through the self-selection process before the grant review process begins; and
- Certify that they did not participate in the discussion or evaluation of any applications with which they have a COI, or the appearance of a COI, after the review process is completed.

CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIALS AND PROCEEDINGS

The applications, proposals, and associated materials made available to reviewers, as well as the discussions that take place during review meetings, are strictly confidential and must not be disclosed to or discussed with anyone who has not been officially designated to participate in the review process. Reviewers must certify that they will maintain the confidentiality of the review and not disclose this information to any other individual except as authorized by American Diabetes Association Research Program staff.