BEST PRACTICES FOR THE ALZHEIMER'S DISEASE RESEARCH CENTERS COST RECOVERY GUIDELINES

General Comment/Justification:

Alzheimer's Disease Research Centers (ADRCs), with their cores, are funded to provide the infrastructure to support both Center-affiliated research projects and non-affiliated research projects. In general, ADRCs do not charge investigators for receiving biospecimens to the extent that NIH Center budgets cover these costs. However, there are exceptions to this general rule. In competing renewal applications, cores generate and justify their budgets according to their best estimates of the future demands for their resources. These expectations are based on future plans of the Center components (other cores and projects), planned affiliations and collaborations, and on past experience (e.g., autopsy rate for the last 5 years). Budgetary projections may not match reality of the demands placed on the Center. Biospecimen requests may be so large that an individual laboratory would be forced to abandon other Center activities in order to prepare the samples. In these situations it is appropriate, allowable, and recommended that Centers develop cost recovery policies to deal with demands when they exceed the budgeted support of the Center. A guiding principle is that no cost recovery program should diminish the essential goal of providing human biospecimens to fuel research into Alzheimer's disease. The best practice guidelines outlined here are intended to apply to ADRC specimens and not necessarily specimens collected through other mechanisms. The following recommendations may guide each Center's development of cost recovery policies.

Definitions:

Program Income is defined as **gross** income—earned by a recipient, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, **income from fees for services performed, and charges for research resources**. The amount of program income earned and the amount expended must be reported on the annual financial report. Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported.¹

Cost recovery refers to the recovery of the expenses of the labor, supplies, and services required to operate biospecimen programs that are **not** already included in the Center budget (prepare, document, ship, etc.) biospecimens. Cost recovery does **not** refer to the sale of the specimen itself. There can be no overlap between specific expenses paid by the grant and paid through program income/cost recovery.

Program Income Alternatives: NIH allows four program income alternatives (additive, deductive, combination and matching). The NIA P30 and P20 Alzheimer Disease Research Center grant mechanisms dictate use of the Additional Costs Alternative in their Notice of Grant Award under the section titled: "Treatment of Program Income." Additional Costs Alternative is equivalent to the Additive Alternative as described in the NIH Grants Policy Statement. The Additive Alternative indicates that any program income is added to funds committed to the project or program and can be used to further eligible project or program objectives. Note that previously, P30 and P50 Alzheimer Disease Research Center grants used the combination alternative.

Recommendations for Best Practices:

Cost recovery policies are subject to scrutiny and should be developed in accordance with Office of Management and Budget (OMB) Circular A21 principles (see Note at end of section). All institutions should

work closely with their own Sponsored Projects Accounting offices and their NIH Grant Management Specialists in developing policies and procedures to comply with the NIH Grants Policy Statement.

Determining and Setting the charges for Biospecimen services:

- Charges or fee schedules for biospecimen services should be based on fair estimates of the actual
 effort (salary and fringe benefits) and costs (supplies, shipping, etc.) associated with sharing the
 biospecimen. These charges should include all costs associated with the service that are not covered
 by the grant award and should be reviewed at least annually and revised to assure that charges are
 covering excess costs.
- 2. Sound cost accounting principles should be employed when setting charges. Personnel costs (salary and fringes), supplies, shipping, equipment rental, and other services (e.g., genome sequencing) are examples of costs that can be considered when setting charges.
- 3. Overhead can ONLY be included in cost recovery charges when applied to services provided to an external client (not to users within your institution).
- 4. Cost recovery may not be limited to the laboratory providing the specimen. Often the burden on data managers to identify appropriate samples based on inclusion-exclusion criteria is significant and cost recovery may also apply to the Data Management Core.
- 5. Cost recovery income should be directed toward support of the operations of the unit expending the effort, i.e., the income should not subsidize an unrelated function or laboratory.
- 6. A tiered system of charges may be considered. That is, the charge may depend on the funding source (federally funded, non-profit foundation or industry) of the research for which the biospecimens are requested. An example of such a system has been developed for the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD). This information is available on the NCRAD site listed as "price structure" under each study's available biospecimens.

Tracking and Reporting of Program Income

Perhaps the simplest method of tracking program income is creation of a program income fund where costs in excess of what the grant can cover (personnel, supplies, etc.) are charged and income from services rendered can be applied. The balance at the end of the budget year will determine which "alternative" is used: Additive or Deductive. The activity on this fund would be the basis of reporting program income on the institution's annual financial report to NIA. If an ADRC has more than one core laboratory generating program income or if a laboratory is funded for similar activities from multiple grants that stipulate different program income alternatives, tracking will be more complicated. The \$25,000 limit on net income is for the entire grant

Reference

(1) NIH Grants Policy Statement (April 2021): Management Systems and Procedures, 8.3.2 Program Income.

Note: The Code of Federal Regulations (https://www.ecfr.gov/cgi-bin/text-idx?SID=bfb0b57d58de9add89103074281ea94a&mc=true&node=pt2.1.200&rgn=div5) establishes uniform cost principles and audit requirements for all Federal awards to non-Federal entities and administrative requirements for all Federal grants and cooperative agreements. The Code of Federal Regulations update of August 13, 2020 supersedes the OMB Circular A21 principles.