BEST PRACTICES FOR THE ALZHEIMER'S DISEASE RESEARCH CENTERS

INTELLECTUAL PROPERTY GUIDELINES

Note: This guideline refers to inventions, as a form of intellectual property, and is not meant to address authorship issues. The need for intellectual property protections is likely low for biospecimen transfers from Alzheimer's Disease Centers where tissue collection has been standardized. Such tissue itself does not represent a unique resource that was created, engineered or invented (e.g. an investigator would be unlikely to 'patent' blood samples). The NIA endorses the least restrictive policies when it comes to sharing biospecimens.[1]

A. Recognize that as custodians of biospecimens, biorepository faculty and staff members are not *a priori* considered inventors under patent law for inventions made using materials distributed by the biorepository. In general, the staff should be informed that one whose sole contribution to an invention consists of the routine collection, handling, storage, and disbursement of biospecimens might not rise to the level of ''inventor'' of an invention. Inventorship is determined by patent law taking into account the role and contributions of individuals involved in the development of the invention and must be considered on a case-by-case basis by trained legal personnel.

B. If true research collaboration is contemplated with the involved biorepository faculty and staff, the nature of that collaboration may qualify for intellectual property rights and can be detailed in intellectual property contractual arrangements or by a material transfer agreement ("MTA").

C. Recognize that biorepositories may not have inherent rights to future intellectual property, but can protect existing rights by contracting with recipient to refrain from filing for intellectual property protection incorporating the biospecimens without express written permission of biorepository. Recipient scientists can protect future intellectual property should they develop inventions from use of banked tissue and data and should notify the biorepository of any intellectual property filings claiming modifications or methods of manufacture or uses of the biospecimens. MTAs can define and secure these rights for both the biorepository and recipient.

D. Ensure through data use agreements and/or MTAs, when applicable, that research data developed using biospecimens are made available to the research community.

References:

1. National Cancer Institute, NCI best practices for biospecimen resources:
    a. 2011 NCI Best Practices website: http://biospecimens.cancer.gov/practices/
    b. PDF of the NCI Biospecimens Best Practice: http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf