**SHILEY-MARCOS ALZHEIMER’S DISEASE CENTER (SMADRC)**

**DATA AND RESOURCE SHARING POLICIES**

All data and biospecimen requests should be made online. The SMADC Research Resource Sharing Hub [www.adrc.ucsd.edu](http://www.adrc.ucsd.edu)) allows investigators to browse extensive documentation of research resources available, query basic statistics on study populations, and submit requests for SMADRC resources.

These policies pertain to NIH funded cohort studies at SMADRC Alzheimer’s Disease Research Center.

Investigators agree to cover all incremental costs associated with biospecimen and data preparation and transfer.

**I. GENERAL POLICIES AND REQUESTS FOR DEIDENTIFIED DATA**

**1. Protection of Privacy**

The SMADC is committed to protecting patient and subject confidentiality. Data are shared according to the minimum necessary principle, whereby disclosures will include only those data necessary to accomplish the aims of the specific project for which data were requested.

To safeguard confidentiality, we require that investigators outside of UCSD sign and adhere to the requirements described in a formal DUA. This Agreement represents a formal legal contract between the UCSD SMADRC and the parent institution of the data recipient.

Recipients of data from the SMADRC studies must guarantee that they are conducting their research in accordance with the rules and regulations established by their local Institutional Review Boards (IRB).

*Investigators receiving SMADRC data or biospecimens may not distribute data or biospecimens to a third party unless approved by the SMADRC.*

Investigators agree not to use or disclose the information other than permitted by the agreement. Investigators agree to use appropriate safeguards to prevent the use or disclosure of the information and agree to report to the UCSD Alzheimer’s Disease Center Repository any uses or disclosures in violation of the agreement to which they become aware.

**2. Application Process**

Investigators must complete and submit a formal proposal as outlined in the online SMADRC Research Resource Sharing Hub. The investigator is required to submit a brief research proposal that includes the rationale, data requested, study design, funding via our resource request form. Data from longitudinal studies can be complex. *Therefore, investigators are strongly encouraged to contact and collaborate actively with one or more SMADRC investigator to ensure best use of data.*

**3. Evaluation of the Proposal**

Requests for data are triaged by the co-chairs of the SMADRC Resource Sharing Committee and subsequently reviewed by SMADRC and non-SMADRC committee members with relevant expertise. Questions that arise in the review process will be relayed to the investigator by the committee chair or SMADRC collaborator. Committee decisions are usually reached within six weeks of submission. Investigators receive an electronic notification of the decision. If the application is approved, the investigator is prompted to complete the DUA. All requests, comments, and decisions are recorded for archival purposes.

**4. Data Release**

In most cases, data will be directly transferred in the form of an Excel or .txt file. The SMADRC Data Management and Biostatistics team has the capability of transferring data in a wide variety of formats should the Excel spreadsheet format not be suitable for the investigator. We aim to provide the dataset within six weeks of receipt of the approved list of variables. Any problems or queries will be discussed between the investigator and the SMADRC Collaborator and/the designated member of the resource sharing committee.

**5. Publication**

*Investigators are responsible for ensuring that all publications using SMADRC data acknowledge the appropriate grant numbers. For example:*

We thank the study participants and staff of the UCSD Alzheimer’s Disease Center. This work was supported by NIA grant P30 AG062429.

Grants should be acknowledged as appropriate in consultation with the SMADRC Collaborator or committee chair.

**II. ACCESS TO PERSONAL IDENTIFIERS FOR STUDY RECRUITMENT**

**1. Application for Access to Personal Identifiers**

Interested investigators must complete and submit a formal proposal as outlined in the online SMADRC Research Resource Sharing Hub. *Because the number of participants is limited and because the SMADRC is dedicated to supporting the most meritorious studies, investigators who are not part of the SMADRC are required to receive written approval from the SMADRC Administrator on a study that recruits SMADRC participants.*

**2. Study Oversight**

The SMADRC has policies in place to ensure that participants are not overly burdened by multiple contacts. We may require that potentially important clinical information obtained by an investigator be shared back with the SMADRC (e.g., results of blood tests, neuroimaging findings). Investigators whose recruitment requests are approved are required to work with SMADRC staff to ensure that enrollment and visit schedule remain updated in real time in the shared operations database.

**III. BIOSPECIMEN REQUESTS**

All data sharing policies and procedures outlined above apply to obtaining ante- and post-mortem biospecimens from SMADRC study participants. *Because the number of biospecimens is limited and were* *accrued over many years at great expense, investigators who are not part of the SMADRC are required to actively collaborate with the Principal Investigator or other representative of the appropriate study if requesting limited resources.*

**1. Biospecimen Distribution Guidelines**

Unlike research data, biologic specimens are of limited quantity and ultimately will be depleted. The SMADRC is committed to ensuring that select, highly limited or rapidly diminishing specimens are carefully distributed for use in scientifically rigorous studies likely to make major contributions to the field of aging and AD research. Evaluations of requests for specimens therefore will take into consideration the availability of and demand for the specimen requested.

**2. Application for Biospecimens and Evaluation of the Proposal**

Investigators must complete and submit a formal proposal as outlined in the online Biospecimen Request

Form. Requests for biospecimens are judged on the scientific merit of the proposed study, the rationale for the use of select SMADRC specimens, the expected impact of study findings, specimen availability, and the value

added to the aging and AD research community in general and the SMADRC in particular.

**3. Study Oversight**

The SMADRC tracks each ID and biospecimen type**.** *Investigators receiving SMADRC biospecimens may only use the biospecimens for the purpose requested in their approved application.* Investigators seeking to use specimens for new purposes must either submit an addendum to their approved application or a new request, which is subject to a new review. *Investigators receiving SMADRC data or biospecimens may not distribute data or biospecimens to a third party unless approved by the SMADRC.*

**IV. Sharing Data Generated by Studies Using SMADRC Biospecimens or Participants**

The NIH and SMADRC are committed to ensuring the timely sharing of data generated on SMADRC participants or biospecimens from SMADRC study participants. *Thus, all new data generated from SMADRC participants or from biospecimens from SMADRC participants using public funds (federal, state, local) must be donated to the parent SMADRC study to be repurposed (i.e., shared with other investigators): a) one year after data generation; or b) at the time of publication, whichever comes first; or c) at a time mutually agreed upon by both parties.* For large datasets, investigators donating data will be added to the Resource Sharing Committee and allowed to vote on data repurposing.