ASPREE ASPirin in Reducing Events in the Elderly

ASPREE data use policy

Version 1.0, May 21st 2020

Version	Date	Comments
1.0	May 21st 2020	Original Version Release. Approved by the Principal Investigators of National Institute on Aging grant 1U19AG062682-01 on <May 21st 2020>.

INTRODUCTION

- This data use policy and its accompanying data use management plan outline the criteria and conditions governing the provision of data from the ASPREE clinical trial longitudinal dataset (2010 to June 2017, version 3, the "**ASPREE dataset**").
- At this time the policy does not govern data from the "Bridge" and "XT" phases of the post-intervention follow-up phase of ASPREE because the data from these phases has not been finalized and curated. Similarly it does not govern sub-study data from these later phases. At such time as new datasets become finalized, this policy and the accompanying data use management plan will be updated accordingly.
- Unless otherwise stated the term "approved project proposal" is used in this policy to mean a project that has been approved by the International Executive Committee, IEC, or a delegated subcommittee of the IEC consisting of two or more ASPREE investigators.
- The aims of sharing ASPREE data are to further collaboration among researchers with interests in a broad range of topics for which data from the ASPREE study can help to answer important research questions, and to publish research findings relevant to older people or to the use of aspirin for prevention.
- Decisions about the provision of ASPREE data to a researcher is ultimately the responsibility of the awardees of the relevant grants that enabled the data collection and its ongoing curation.
- The procedures outlined in this policy and the accompanying management plan reflect our obligations specified by the Monash Committee for Ethical Research in Humans and are in keeping with the Australian National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research.
- It is noted that individual researchers are bound by the regulations imposed by their institutions and the stipulations required by the ethics committees approving particular project(s).
- These procedures recognise our commitment to protecting the privacy of study participants who continue to provide their private health data to the research team as part of ASPREE-XT, which is due to complete in 2024, and are informed by the US Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.
- There are six modes of access to ASPREE data and each is outlined below with relevant considerations.

1. Access to the ASPREE dataset at Monash University and the Berman Center

- Awardee institutions for the National Institute on Aging grant 1U01AG029824-01A2, the primary funding source for the ASPREE clinical trial, included Monash University and the Berman Center (HHRI) and the Principal Investigators were Dr John McNeil and Dr Anne Murray.
- The ASPREE dataset will be available in a secure location at each of the two awardee institutions for exploratory analysis by researchers within the institution as allowed by the institution's Principal Investigator listed above.
- Each Principal Investigator will be responsible for managing this access to the ASPREE dataset in keeping with the principles of this data use policy, including ensuring the data requested will be stored in a secured environment and will not be shared with others except listed co-investigators on that analysis.
- Use of the ASPREE dataset [for any purpose other than exploratory analysis] requires an approved project proposal.
- This approval is required prior to the submission of the work for presentation or publication of any form.

2. ACCESS VIA THE ASPREE SAFE-HAVEN

- The safe-haven will be the location of the final version of the ASPREE dataset
- Access via the safe-haven is the default approach for data access.
- Access requires the signing of a MOU by the Investigator within the ASPREE Safe Haven.
- Access to the safe haven will be provided to approved project proposals for research that has ethics approval.

3. ACCESS OUTSIDE THE SAFE-HAVEN

- Access to ASPREE data extracts may be requested by researchers outside of Safe Haven for analysis related to approved project proposals,

- to include in meta-analyses,
- to use analytical tools that are unavailable in the Safe Haven such as those needed for handling large-scale genomics and imaging analyses with linked phenotypic information, or online disease risk calculators,
- to enhance speed of collaboration in the data analysis process when this occurs in investigator teams,
- to facilitate analyses being conducted at remote sites.

- In such cases the data that is provided will be limited to the study participants and data fields that are essential for completion of the approved project, and de-identification of the data will be ensured.

- This type of request will require a data use agreement (DUA) approved by both Monash University and The Berman Center (HHRI)

4. LINKAGE TO EXTERNAL DATA SOURCES

- Personal identifiers (such as name, address and date of birth) will be required to undertake linkage with external data repositories such as disease registries.

4.1 Linkages for the sole purpose of ingress of data from a registry to become part of the ASPREE resource

- Ethics approvals will be required for linkages for approved project proposals to receive data from a registry and for any agreements required by the external party to be completed by Monash University, and/or the Berman Center (HHRI) and the authority managing the database to be linked. A new Linkage study will be created by the linkage (which will be named to identify the linkage database).
- The linkage process will be undertaken in a secure environment.
- The new data will reside in the ASPREE database and will be available from there as a defined Linkage study, with access governed by this policy.

4.2 Linkages involving egress of ASPREE data to be linked with registry data that will reside outside the ASPREE database.

- Linkages for approved project proposals will require ethics approval, and a DUA between Monash University, the Berman Center (HHRI) and the authority managing the database that is to be linked. The DUA for the new Linkage study should nominate an ASPREE-XT Principal Investigator with responsibility for directing the resulting Linkage study.
- The linkage process will be undertaken in a secure environment and the resulting linked dataset will be de-identified and stored in a secure location that is separated from the personal identifiers.
- With the agreement of the external data repository, a copy of data fields in the linked dataset that originated from the external source may be transferred to the ASPREE database and considered part of the ASPREE resource for future research, and will be governed by this policy as a Linkage study.

5. ACCESS TO SUB-STUDY DATA

This policy applies to ASPREE sub-studies since such studies involve ASPREE participants and their existence is reliant on the original ASPREE study. In the case of sub-study data, in addition to approvals required from the International Executive Committee or a delegated subcommittee of two or more ASPREE investigators, the Principal Investigator of the sub-study must also provide approval.

6. Making extracts of ASPREE data publicly available

In some circumstances it will be required to make parts of the ASPREE dataset available, for example basic demographic characteristics such as age and sex or simple phenotypic outcomes such as occurrence of a particular disease. This may occur for example as part of a data release for publicly

accessible repositories of participant-level information and phenotype. This may also be required to accompany valuable detailed data such as participant genomic signatures. In these circumstances it is expected that a DUA will be required and the detailed requirements will be assessed on a case-by-case basis during the process of obtaining an approved project proposal.