I. MarkVCID General Sharing Policies and Procedures

A. Overview

MarkVCID research is openly shared both within and outside the MarkVCID consortium to the greatest extent practical. As per the MarkVCID Consortium's Charter, MarkVCID investigators are granted broad access to MarkVCID data, samples, analytic tools, and other resources with relevant permissions in place. The policies and procedures described in this document concern all investigators and coordinators of participating research sites, external researchers, and Coordinating Center staff throughout the grant period who oversee and conduct research. MarkVCID data and samples may also be shared with external collaborators in compliance with Consortium's external data sharing policies. Collaborators agree not to sell participant biosamples or data for profit. However, any scientific knowledge gained from the biosamples and/or data may be used in the future to develop products that could be used for profit. Publications resulting from the use of MarkVCID data are expected to acknowledge the MarkVCID consortium as outlined in the MarkVCID Data Use and Publications (section II).

B. Data and Biosample Request Procedures

All internal and external data and biosample requests are made by submitting a Project Proposal Form. The form requires a project overview with specific aims, background, methods and power estimate for the proposed project, a description of the requested data and/or biosamples, assays, experiments to be conducted, and plans for publication.

Data requests will be reviewed by the Sharing Subcommittee and biosample requests will be reviewed by the Fluid-Based Biomarkers Subcommittee. Reviews will be based on overall scientific rationale, overlap with already approved analyses, and in the case of biosample requests, the scientific priority of the study relative to the quantity of available biosamples. Subcommittee recommendations will then be reviewed and approved or disapproved by the Steering Committee (site PIs and NINDS). Internal data or biosample requests related to prespecified biomarker kits primary hypotheses are exempt from the above review process.

MarkVCID Internal Investigators

All MarkVCID research sites will sign a Consortium Research Agreement governing the sharing of data and biosamples and agree to adhere to the letter and spirit of the Agreement. Data deposited into MarkVCID data systems by the research sites will be available to all members of MarkVCID, in accordance with the rules and regulations outlined in this policy and the MarkVCID Research Agreement.

External Investigators

Data will be shared with external investigators after review of the Project Proposal Form and additional data and/or material use agreements are signed. Data distributed by MarkVCID cannot be redistributed.

If the request is approved by the Steering Committee, external users will sign a MarkVCID Data Use Agreement to gain access to the data. If biosamples are requested, external users will execute a Material Transfer Agreement (MTA) with the institution(s) providing samples. Electronic data stored by the MarkVCID Consortium repository will be available to the investigator within approximately three weeks after approval of the project by the appropriate committee and principal investigators, and the signing of the Data Use Agreement. Biosamples will be shipped within approximately three months. Investigators requesting biosamples for secondary analyses will absorb the cost of shipping samples from involved MarkVCID institutions to the receiving lab. Access to electronic data and biosamples not held by the MarkVCID repository must be made to the relevant body and may take longer to access.

II. MarkVCID Data Analysis & Publications

A. Overview

The analysis and publications policy governs works generated through the use of MarkVCID data and biosamples. This policy applies to all original research papers, abstracts, platform presentations, posters, press releases, and any other material generated for public dissemination through the use of MarkVCID data and biosamples.

Works are characterized throughout this policy as follows:

Internal Primary and Secondary MarkVCID Generated Publications
All consortium investigator-generated work necessary to fulfill the specific aims or related to the overall scope of MarkVCID (primary publication), or work resulting from the use of data not directly necessary to fulfill the specific aims or overall scope of MarkVCID Research Projects (secondary publication).

External Publications
Work by non-MarkVCID investigators that incorporates MarkVCID data and/or biosamples unrelated to the specific aims of the MarkVCID consortium.

B. Internal Primary Publications

Named author designation
Named authorship on MarkVCID manuscripts will require meeting all four criteria of the International Committee of Medical Journal Editors (ICMJE).

1. Substantial contributions to the conception or design of the work; or the acquisition, or interpretation of data for the work; and
2. Drafting the work or revising it critically for important intellectual content; and
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The first author or designated senior author has the principal responsibility for writing the manuscript and will also oversee the process of submitting the manuscript, corresponding with the publisher, revisions, and proofreading the final page proofs. The first author should determine authorship, and all coauthors should agree to be cited and to the placement of their names in the citing of coauthors. Not all coauthors of MarkVCID publications are required to be members of MarkVCID.

In addition to review by all coauthors (named and unnamed) per standard scientific practice, all internal primary MarkVCID manuscripts will be provided to the Steering Committee for review at least four weeks prior to anticipated submission. In addition to manuscript content, the Steering Committee will review and approve authorship citation and feedback will be returned to the first author.

Group designation of unnamed authors
For Internal Primary manuscripts, “for the MarkVCID Consortium” must be designated on the title page after the coauthors’ names to designate unnamed authors including PIs, CoIs, and senior research personnel. These are individuals who meet the ICMJE criteria, are actively involved in site procedures, but are judged by the lead author to have had a limited role in the specific manuscript. Unnamed authors will appear at the end of the manuscript and be appropriately associated with the manuscript in PubMed.

Acknowledgements
The lead author must include in the Acknowledgements section of the manuscript a link to https://markvcid.partners.org/acknowledgements that lists all site personnel who are involved in site procedures.

There may also be instances when collaborations with nonmembers, including other NIH- and non-NIH-funded consortia, will contribute significantly to a publication, and these individuals, and consortia, should be listed as coauthors or in acknowledgements as applicable.

All publications, posters, oral presentations at scientific meetings, seminars, or any other forum in which results of this co-funded research are presented must include a formal acknowledgement of the NINDS/NIA support, the MarkVCID consortium, and cite the NINDS grant number/s (see Data Use Agreement, section XIV.3).

Internal MarkVCID investigators will apprise the MarkVCID CC of acceptance or rejection of all submitted manuscripts. If accepted, full citation of all published manuscripts must be provided to MarkVCID upon electronic or print publication. See Data Use Agreement section XIV for more guidance.

Internal secondary publications will follow the procedures outlined below for external publications.

C. External and Secondary Internal Publications

External investigators using MarkVCID data and/or biosamples in analyses or publications, will be asked to agree to the following as part of the Data Use Agreement (p.5-7):

- MarkVCID personnel meeting ICMJE authorship criteria will be included in the authorship list; this may include listing the names of the MarkVCID leadership, key senior contributors to the MarkVCID project design and organization, and up to three collaborators from each MarkVCID research site (e.g. the site PI/MPI and one to two other individuals designated by the site PI).

- All manuscripts will acknowledge the role of MarkVCID in providing the data using the language recommended by MarkVCID and note the data used (see Data Use Agreement, p.5-7). Manuscripts will be submitted to the MarkVCID Coordinating Center for administrative review two weeks prior to submission. The purpose of this review will be to confirm that all the above requirements are met.

- All other posters, oral presentations at scientific meetings, seminars, or any other forum which result of this co-funded research must include a formal acknowledgement of the NINDS/NIA support, the MarkVCID consortium and MarkVCID data used, and cite the NINDS grant number/s (see Data Use Agreement section XIV) and MarkVCID Acknowledgements.

- External investigators will apprise MarkVCID of acceptance or rejection of all submitted manuscripts. If accepted, full citation of all published manuscripts will be provided to MarkVCID upon electronic or print publication.

- A copy of the manuscript will be provided to MarkVCID upon publication of the manuscript. If permitted by the journal, the article or link to the article will be available online at the MarkVCID website.

D. Substandard Reports and Data Use Violations

Most users of MarkVCID data are expected to follow these guidelines in good faith and adhere to scientific publishing standards. The following apply to unusual circumstances:

Manuscripts not Meeting Accepted Scientific Standards

If the coordinating center's review of a proposed manuscript reveals that it does not meet accepted scientific standards, concerns will be brought to the Steering Committee who may recommend to the authors that the manuscript not be submitted without significant revision or that the authors publish a statement to the effect that while MarkVCID data were used, MarkVCID did not find this manuscript at a sufficient scientific standard to warrant submission for publication.

Failure to Follow Data Use Agreement

If users inadvertently violate the Data Use Agreement, it is likely that they will self-correct as infractions are discovered. If the MarkVCID Steering Committee and NINDS find that users have willfully violated the Data Use Agreement, access to MarkVCID data will be revoked and NINDS policy will be enforced as applicable (https://grants.nih.gov/grants/policy/data_sharing/index.htm).

Fraudulent Use of Data

Should the Consortium discover an attempt to publish data obtained through fraudulent access to MarkVCID data, further access will be revoked, and the incident and user will be reported to the appropriate NIH office.

Journal Objections

The Consortium can authorize exceptions to the acknowledgement policy or can negotiate with journal editors as needed on a case-by-case basis.

E. Conflict Resolution

The Steering Committee, in consultation with the External Advisory Committee, will resolve disputes arising from the MarkVCID Sharing and Publications Policy directly with those involved whenever possible. When this is not possible, a dispute-resolution panel composed of three members (one member each from the Steering Committee, NINDS, and External Advisory Committee) will settle the dispute by a majority vote. This decision can be appealed in accordance with PHS regulation 42 GFR Part 50, subpart D and DHHS regulation 45 CFR part 16.

I. The party receiving access to the Data (as defined below) is _____ ("Recipient"), a staff member or employee of_____ ("Institution"), with a principal place of business at _____. The party holding the Data is The General Hospital Corporation d/b/a Massachusetts General Hospital ("Holder"), with a principal place of business at 55 Fruit St, Boston, MA 02114.

II. Holder is a member of and Coordinating Center for the National Institutes of Health ("NIH") Biomarkers Consortium for Vascular Contributions to Cognitive Impairment and Dementia ("MarkVCID"). MarkVCID was launched in 2016 by the NIH's National Institute of Neurological Disorders and Stroke and National Institute on Aging, and consists of research groups across the United States ("Consortium Members"). The primary goal of MarkVCID is to generate a suite of validated biomarkers ready for application to clinical trials aimed at identifying disease-modifying therapies for VCID.

III. Holder has executed a Consortium Agreement with the Consortium Members to govern the transfer and use of MarkVCID data generated the Consortium Members.

IV. For purposes of this Data Use Agreement ("Agreement"), the "Data" refers to data generated by the Holder and Consortium Sites and stored in Holder's MarkVCID database and authorized pursuant to the Consortium Agreement to be shared with certain external parties. All Data is de-identified within the meaning of the United States Health Insurance Portability and Accountability Act ("HIPAA") privacy regulations.

V. Holder wishes to provide the Data and Recipient requests access to the Data for a scientific research project specifically outlined in Recipient's data request application to Holder (the "Application").

VI. The period of this Agreement is from the date of signature to the conclusion of Recipient's research project outlined in the Application ("Term") unless earlier terminated. Either party may terminate this Agreement with thirty (30) days written notice to the other party. Upon expiration or early termination of this Agreement, Recipient shall destroy the Data provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

VII. Recipient agrees to not distribute Data to other individuals inside Recipient's Institution unless such parties have agreed in writing to the terms and conditions contained herein prior to transfer. Recipient shall not transfer the Data outside of Recipient's Institution. Investigators at other institutions must apply directly to the MarkVCID website to obtain Data.

VIII. By accepting this Agreement, Recipient warrants that all Institution-required approvals are in place for the use of the Data. Such approvals may include, as applicable, Institutional Review Board ("IRB") approval and approval of the terms and conditions of this Agreement.

IX. In consideration of Holder making available the Data to Recipient, Recipient agrees as follows:

1. To use and disclose the Data only as permitted by this Agreement and the IRB-approval, as applicable, or as required by law.
2. To use and disclose the Data only as stipulated in Recipient's Application.
3. To use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement.
4. To, throughout the Term, warrant compliance with all applicable Federal, State, and local laws and regulations.
5. To not to attempt to re-identify the Data. If such re-identification occurs, Recipient shall immediately inform Holder and destroy all copies of the Data. Any attempt to re-identify Data will result in the Recipient being barred from further access to Data on the MarkVCID website, updates to Data, or future Mark VCID Data.
6. To refrain from using the Data to identify or to contact individuals;
7. To not sell Data or otherwise use or disclose Data for a commercial, marketing or fundraising purpose.

X. Recipient agrees to report to Holder and to Federal and state agencies, as appropriate, any use or disclosure of the Data not provided for by this Agreement of which it becomes aware, including, without limitation, any unauthorized disclosure to subcontractors, within five (5) days of its awareness.

XI. It is the policy of the MarkVCID Consortium to make analyzed data available to investigators as quickly as possible. However, data analysis for this project is expected to take years as methods for analysis of these datasets evolve. Therefore, Recipient acknowledges that Data might be preliminary and that results may change as new methods of analysis are implemented.

XII. Recipient further acknowledges that Data is being provided AS IS, WITHOUT WARRANTY OR REPRESENTATIONS (including as to merchantability, fitness for a particular purpose, accuracy, efficacy, completeness, capabilities or safety, or non-infringement on third party proprietary rights or any other warranties or representations whether express or implied); all warranties and representations with respect to the Data are hereby excluded to the greatest extent permissible by law. Neither Holder nor its employees, servants or agents shall have any liability whether in contract, tort, and statute or otherwise in connection with Recipient's use of the Data. Recipient uses the Data at Recipient's own risk.

XIII. If Recipient publishes abstracts using Data, Recipient will cite MarkVCID as the source of data and the MarkVCID funding sources in the abstract as space allows.

XIV. If Recipient publishes manuscripts using Data:

1. Recipient will include language similar to the following in the methods section of such manuscripts in order to accurately acknowledge data gathering by the MarkVCID personnel. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below, however inclusion of some variation of the language shown below is mandatory and must be approved by Consortium.

   Data used in the preparation of this article were obtained from the (NIH) Biomarkers Consortium for Vascular Contributions to Cognitive Impairment and Dementia (MarkVCID) database. MarkVCID was launched in 2016 by the NIH's National Institute of Neurological Disorders and Stroke (NINDS) and National Institute on Aging (NIA), and consists of research groups across the United States. The primary goal of MarkVCID is to generate a suite of validated biomarkers ready for application to clinical trials aimed at identifying disease-modifying therapies for VCID. For up-to-date information, see www.markvcid.org.

2. Recipient will include language similar to the following in the acknowledgements section of such manuscripts to acknowledge Consortium Members:

   Data used in preparation of this article were obtained from the MarkVCID consortium. A complete listing of MarkVCID investigators can be found on https://markvcid.partners.org/acknowledgements.

3. Recipient will acknowledge funding by NINDS/NIA as part of the MarkVCID Consortium in all publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this co-funded research are presented similar to the following:

   MarkVCID1 Research Projects (RFA-NS-16-019, RFA-NS-16-020)
   If the research addresses the specific aims and overall scope of the **MarkVCID1 Research Projects** (funded by RFAs) - Data collection and sharing for this project was funded by NINDS/NIA as part of the MarkVCID Consortium *(U24NS100591, UH2NS100599, UH2NS100605, UH2NS100588, UH2NS100608, UH2NS100606, UH2NS100598, UH2NS100614).*

   MarkVCID2 Research Projects (RFA-NS-21-005, RFA-NS-22-017)
   If the research addresses the specific aims and overall scope of the **MarkVCID2 Research Projects** (funded by RFAs) - Data collection and sharing for this project was funded by NINDS/NIA as part of the MarkVCID Consortium *(U24NS100591, UF1NS100599, UF1NS125513, UF1NS100588, UF1NS100608, UF1NS125488, UF1NS100598, UF1NS100614, UF1NS125417, UF1NS125512)*.

   Research Outside the Specific Aims and Overall Scope of MarkVCID1/2 Research Projects

   If the research is outside of the specific aims and overall scope of MarkVCID1/2 Research Projects (not funded by RFAs) - Data collection and sharing for this project was funded by NINDS/NIA as part of the MarkVCID Consortium (U24NS100591).

4. Recipient will note the version of Data used to compose the abstract or publication and will check the database to determine if updated data has been provided prior to submission of any material for publication.

5. Recipient will submit all manuscripts to Holder prior to submitting to a journal. This review will not be a scientific review, but is intended to ensure that items 1-3 above are correctly implemented. Holder will maintain confidentiality of the manuscript and will complete its review within two weeks.

XV. The determination of the rights of ownership and disposition of inventions resulting from the performance of the research under this Agreement shall be made in accordance with the US standard Rules of inventorship and subject to the provisions of 37 CFR 401, et. seq.

XVI. Recipient understands that failure to abide by these terms and conditions will result in termination of its privileges to access Mark VCID Data.

Full Name (Print): _____

Full Name (Sign): _____

Title: _____

Date: _____