

National Institutes of Health (NIH) Biomarkers for Vascular Contributions to Cognitive Impairment and Dementia Consortium (MarkVCID)

l.	The party receiving access to the Data (as defined below) is	(	"Recipien	ıt"), a staf	f memb	er
	or employee of	("Institution"),	with a	principal	place	of
	business at The party holding the Data	is The Genera	l Hospita	I Corpora	tion d/k	o/a
	Massachusetts General Hospital ("Holder"), with a principal place of busine	ss at 55 Fruit S	St, Boston	, MA 021	14.	

- 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:
  - 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 <a href="https://markvcid.partners.org/acknowledgements">https://markvcid.partners.org/acknowledgements</a>.

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 <u>MarkVCID1</u> 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 <u>MarkVCID2</u> 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:	
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