



SINGLE VENTRICLE SOURCE

ADDITIONAL VENTURES FOUNDATION SINGLE VENTRICLE SOURCE Data Use Certification Agreement

This Data Use Certification Agreement (“**Agreement**”) is made as of _____, 20__ (the “**Effective Date**”) by and between Additional Ventures Foundation, a California nonprofit public benefit corporation (“**Additional Ventures**”) and **the undersigned institution or company** (“**Requester**”). This Agreement shall apply only in the event that Requester is approved for and provided access to the Dataset by Additional Ventures. Additional Ventures and Requester are each referred to herein as a “party”, and collectively, as the “parties”.

In consideration of the mutual covenants, conditions, and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Background

Overview

Additional Ventures is focused on curing single ventricle heart disease (“**SVHD**”) through transformative research and strategic investments that revolutionize treatment and care for the patients and families suffering from the burden of SVHD (the “**Mission**”). In furtherance of the Mission, Additional Ventures has sponsored an Institutional Review Board (“**IRB**”) approved study under a research protocol titled “Single Ventricle SOURCE” (the “**Study**”). As a result of the Study, Additional Ventures has compiled a clinical and genetic biorepository of data and biospecimens collected from individuals with SVHD and from their immediate family members. Using these data and biospecimens, Additional Ventures, through its vendor, Gencove, has created a database of de-identified genetic, clinical, and survey data known as “reSOURCE dataset.” The reSOURCE dataset, whether accessed and/or used in whole or in part, as it may be updated from time to time to exclude or include additional de-identified data (the “**Dataset**”) is securely maintained by Additional Ventures’ authorized designee on the SOURCE data platform (the “**Platform**”).

Data Access Committee

The Dataset is intended to serve as a broadly available resource for the research community. Accordingly, Additional Ventures wishes to provide access to the Platform and the Dataset to

academic institutions and corporations and their respective employees who are qualified researchers (including, any authorized subcontractors) whose research proposals have been approved by the SOURCE Data Access Committee convened by Additional Ventures (the “**DAC**”) pursuant to the terms and conditions of this Agreement.

The DAC will evaluate requests from each Requester and their employee who is a qualified researcher (the “**Primary Approved User**”) primarily for the following:

- consistency of each Project (as defined in Section 2) with the Research Subject Consent Form (the “**Consent**”) obtained from each Study participant; and
- assurance of privacy and security protections by each Requester and Primary Approved User that are consistent with the Consent, this Agreement, and applicable laws and regulations.

2. Dataset Use & Access

Research Use

After the Effective Date, the Platform may be accessed and the Dataset used by Requester, the Primary Approved User and each Approved User (as defined in Section 19) for one or more specified research purposes approved by the DAC (each, a “**Project**”) that align with the Mission, the Study, and Additional Ventures’ goals of studying genetic, clinical, and environmental contributors to SVHD and related conditions. A Project may have a scope beyond the initial focus of the Study, as long as such use aligns with the Consent, this Agreement, the applicable DAC approval, and applicable laws and regulations. Research use of the Dataset under this Agreement is allowed solely in connection with a Project. Requester and the Primary Approved User hereby certify that the description of each Project in the “Research Use Statement” section of Requester’s and/or the Primary Approved User’s Data Access Request (“**DAR**”) is truthful and accurate (the “**Research Use Statement**”). Each Project will require submission of a separate DAR by Requester and the Primary Approved User. New uses of any portion of the Dataset outside of those described in the DAR will also require submission of a new DAR. Modifications to any Project will require submission of an amendment to the applicable DAR. For clarity, a Project may be described broadly and may encompass multiple related analyses, provided such analyses remain consistent with the Research Use Statement and the consent/DUA restrictions.

Controlled Access

Access to the requested portion of the Dataset for a Project is granted for a period of one (1) year from the Effective Date, with the option to renew such access or close-out each Project at the end of the one year anniversary of the Effective Date, unless this Agreement is terminated earlier in accordance with Section 11 (“**Access Period**”).

Access to the Dataset is provided by Additional Ventures at no cost. Requester acknowledges that costs associated with its use of the Platform, including applicable compute, storage, and data egress charges, are the responsibility of the Requester and may be billed separately in accordance with the applicable Platform billing arrangements.

Download/export of the Dataset is permitted (a) solely for purposes of each Project described in each DAR, (b) only to secure computing environments that meet the requirements outlined in this Agreement, and (c) only for access and use by Requester, the Primary Approved User and Approved User(s). Requester and the Primary Approved User shall, at all times, remain responsible for all such authorized and controlled access by each Approved User as provided in this Agreement. Except as provided in this Agreement, the Dataset may not be shared, redistributed, or transferred to any third party that is not an Approved User identified in Appendix A without prior written authorization from Additional Ventures.

If contractor services are to be utilized by Requester and/or the Primary Approved User, they shall provide a brief description of the services that such contractor will perform (e.g., data cleaning services) in the Research Use Statement. Requester and the Primary Approved User shall include in any agreement with such contractor(s) the requirement that such contractor(s) and their employees who have access to the Platform and the Dataset adhere to the terms and conditions of this Agreement. These requirements apply whether such contractor carries out their services at Requester's or such contractor's own facility or secure computing environment.

Requester and the Primary Approved User further understand, acknowledge, and agree to the following:

- Additional Ventures and the DAC may reject DARs, request revisions to DARs, and terminate ongoing Projects if Additional Ventures or the DAC assesses that a Project has significant potential to cause harm to Study participants, or their families, or groups and populations of which they are a part, or for any reason at Additional Ventures' sole and absolute discretion.
- They are responsible for ensuring that all uses of the Dataset are consistent with all relevant institutional policies and procedures of Requester (e.g., those with respect to human subjects research, information technology, and technology transfer), including IRB approval if required, for managing access to and use of the Dataset.
- In using the Dataset, they are not aware of any significant potential for a Project to cause harm to Study participants, or their families, or groups and populations of which they are a part.
- In using the Dataset, if they become aware of any significant potential for a Project to cause harm to Study participants, or their families, or groups and populations of which they are a part that they will immediately notify Additional Ventures via contact@svsource.org.

Approved Users may include collaborators affiliated with institutions other than the Requester, provided that such individuals are identified in Appendix A and their participation is consistent with the approved Research Use Statement. Requester and the Primary Approved User shall remain responsible for ensuring that all Approved Users, regardless of institutional affiliation, comply with the terms and conditions of this Agreement, including all applicable data access, use, confidentiality, and security requirements.

3. Reports

The Primary Approved User agrees to provide annual Progress Updates (as defined in Section 19) to Additional Ventures and the DAC as part of the annual Project Renewal or Project Close-out (both as defined in Section 19) processes, prior to the expiration of the applicable Access Period. The Primary Approved User who is seeking such renewal or close-out of a Project shall complete the appropriate online forms and provide specific information such as how the Dataset has been used by such Primary Approved User and all Approved User(s) identified in Appendix A, including publications or presentations that resulted from such use; a summary of any plans for future research use (if the Primary Approved User is seeking renewal); any violations of the terms of controlled access described in this Agreement and any implemented remediation by Requester; Derived Data; and, to the extent permitted by Requester's institutional policies and confidentiality obligations, a non-confidential, high-level summary regarding any and all inventions, discoveries, and technologies (whether or not patentable or registrable under patent, copyright, trademark, or similar statutes), works of authorship, mask works, designs, formula, processes, compositions of matter, computer programs, databases, know-how, ideas, and information (collectively, "IP") generated from use of the Dataset ("Arising IP"). The Primary Approved User may also include general comments regarding suggestions for improving the data access process in general. Information provided in Progress Updates helps Additional Ventures evaluate program activities and other efforts to provide ongoing stewardship of its data-sharing activities.

4. Compliance with Laws

Compliance with Applicable Laws

Requester is responsible for ensuring that each Project is carried out in compliance with all applicable laws, rules and regulations, each as amended from time to time, including those applicable to protecting the rights and privacy of human trial subjects (including, to the extent applicable, approval of any human trials by an appropriately constituted IRB), those applicable to anti-terrorism, anti-bribery, export control (including those applicable to exportation of personal data, health data, technical data, computer software, laboratory prototypes, and other commodities, including the Arms Export Control Act, 22 U.S.C. Section 2751 et seq. and the Export Administration Act of 1979, as amended), and those relating to non-discrimination, sexual harassment, and equal employment opportunity.

Without limiting the generality of the foregoing, Requester and the Primary Approved User shall, and will ensure that each Approved User shall, comply with the terms and conditions of this Agreement and applicable law, and implement and maintain safeguards consistent with the National Institutes of Health ("NIH") [Genomic Data User Code of Conduct](#) (the "**Code of Conduct**"), and [NIH Security Best Practices for Users of Controlled Access Data](#) ("**NIH Controlled-Access Practices**"), or if applicable, the Non-US Requirements (as defined in Section 19) for any such user residing outside the United States.¹

Data Protection Laws

The Dataset is de-identified. Notwithstanding the foregoing, in the event that any aspect of the

¹ NIST Special Publication 800-171 "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations"

Dataset or Derived Data (as defined in Section 19) becomes, through any mechanism, means, or occurrence, identifiable to an individual natural person, and is thus “Personal Data” (including, where applicable, “Special Categories of Personal Data” such as data concerning health) within the meaning of Regulation (EU) 2016/679 (the “**General Data Protection Regulation**” or “**GDPR**”), the UK GDPR, or any other similar term under any applicable data protection law, including a state or federal U.S. data privacy or security law or regulation, including the privacy regulations implementing the Health Insurance Portability and Accountability Act (“**HIPAA**”) (collectively, “**Data Protection Laws**”), Requester and the Primary Approved User shall process, and shall ensure that all Approved Users process, such data in compliance with such Data Protection Laws.

With respect to the Dataset and any Derived Data accessed, used, downloaded/exported, shared, or generated under this Agreement, Requester and the Primary Approved User shall, and will ensure that each Approved User shall:

- not attempt to re-identify any individual, directly or indirectly;
- not use the Dataset or any Derived Data, alone or in combination with any other datasets, for the purpose of re-identifying, contacting, or attempting to identify any individual Study participant; and
- not contact any Study participant under any circumstance, including any attempt to return individual or secondary research or other findings to any such participant.

For clarity, Requester and the Primary Approved User may combine the Dataset and/or Derived Data with other datasets for research purposes consistent with the applicable DAR, provided that such combination is not used to identify or contact, or attempt to identify or contact, any study participant, and does not reasonably increase the risk of re-identification.

Requester and the Primary Approved User shall ensure that any Derived Data or research outputs shared outside the group of Approved Users do not contain Individual-level Data or information that could reasonably enable re-identification of Study participants. Permissible disclosures may include summary statistics, aggregate counts, and other non-participant-level outputs that have been assessed to mitigate re-identification risks under applicable Data Protection Laws. Any disclosure of Individual-level Data outside of the group of Approved Users requires prior written authorization from Additional Ventures and must comply with this Agreement.

Non-Debarment

Requester agrees that neither it, nor the Primary Approved User nor any Approved User or any other person or entity that participates in a Project has been debarred or otherwise disqualified by any regulatory authority or under U.S. federal procurement or non-procurement laws.

5. Data Confidentiality; Use of AI

Data Confidentiality

Requester and the Primary Approved User acknowledge that the Dataset is controlled-access research data that has not been publicly released and must be protected from unauthorized use or disclosure. From the Effective Date and until the Dataset has been destroyed in accordance with Section 11, Requester, the Primary Approved User or any other Approved User shall impose

and comply with appropriate safeguards to prevent the use and disclosure of the Dataset other than as permitted by this Agreement. Without limiting the foregoing, Requester and the Primary Approved User shall treat all aspects of the Dataset in accordance with Requester's internal security procedures, the Code of Conduct, and NIH Controlled-Access Practices, or if applicable, the Non-US Requirements, and all other applicable laws and regulations, and treat the Dataset with the same degree of care regarding secrecy and confidentiality as Requester uses with respect to its own confidential and proprietary information of a like nature.

Notwithstanding the foregoing, Requester and Primary Approved User may disclose any aspect of the Dataset as may be required pursuant to an order of a court of competent jurisdiction or a valid subpoena, provided that Requester and Primary Approved User first notify Additional Ventures and cooperate reasonably with Additional Ventures in its efforts to contest or limit the scope of such disclosure.

Use of AI

Requester and Approved Users may use artificial intelligence and machine learning methods, including training and fine-tuning models, solely for the DAC-approved Project and only in secure computing environments compliant with this Agreement. Requester and the Primary Approved User shall not, and shall ensure that all Approved Users do not, upload, disclose, transmit, or otherwise make available any Individual-level Data (or any Dataset extracts or Derived Data maintained in participant-level form) to any **"Public AI Tool"** (as defined in Section 19) without Additional Ventures' prior written consent. This restriction does not prohibit use of AI/ML tools operated within Requester's (or its contracted service provider's) secure environment for the DAC-approved Project, nor the generation, retention, or disclosure of aggregate, non-participant-level outputs (including model parameters, non-participant-level embeddings, and summary statistics) that do not reasonably enable re-identification.

6. Data Security

If Requester, the Primary Approved User, or any Approved User, expect to use a CSP (as defined in Section 19) outside of the Platform and/or a Third-party IT system (as defined in Section 19), Requester and the Primary Approved User must provide a Cloud Use Statement ("**CUS**"), agree to secure the relevant portions of the Dataset in accordance with NIH Controlled-Access Practices, and the Non-US Requirements. The CUS should state the name of the CSP and/or Third-party IT system, their security standards, and how the CSP and/or Third-party IT system will be used to carry out a Project or, if applicable, the Non-US Requirements.

With respect to the Dataset, Requester and the Primary Approved User shall, and will ensure that each Approved User shall:

- store such Dataset in secure computing environments, e.g., HIPAA and/or GDPR-compliant servers or Cloud Computing (as defined in Section 19) platforms meeting equivalent standards;
- implement technical safeguards against unauthorized access to such Dataset, including encryption at rest and in transit;
- limit access to such Dataset only to the Primary Approved User and Approved

- User(s) each of whom must use an individual account as sharing credentials or using shared lab accounts is prohibited under this Agreement; and
- if exporting such Dataset outside of the Platform, adhere strictly to the standards of NIH Controlled-Access Practices or, if applicable, the Non-US Requirements.

With respect to the Dataset, Requester and the Primary Approved User shall notify Additional Ventures via contact@svsource.org of any unauthorized data sharing, breach of data security, or inadvertent data release (each, a “**Security Incident**”) within five (5) business days of when the incident is identified. As permitted by applicable law and regulations, such notifications shall include any known information regarding the Security Incident and a general description of the activities or process in place to define and remediate the situation fully. Within three (3) business days of any such notification, Requester and the Primary Approved User agree to submit to the DAC a detailed written report including the date(s) and nature of the Security Incident, actions taken or to be taken to remediate any identified issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action. Requester and the Primary Approved User shall provide any additional documentation requested by Additional Ventures or the DAC, including verifying that appropriate remediation plans have been implemented. Requester and the Primary Approved User shall consider in good faith incorporating any changes recommended by Additional Ventures or the DAC to Requester’s proposed corrective or preventive actions. Repeated violations or unresponsiveness to Additional Ventures’ requests may result in termination of this Agreement.

7. Intellectual Property; Disclaimer

By requesting access to dataset(s), the **Requester** and **Approved Users** acknowledge the intent of Additional Ventures that anyone authorized for research access through the **DAR** follow the intellectual property (IP) principles as summarized below:

- Achieving maximum public benefit is the ultimate goal of data distribution through the reSOURCE dataset. Additional Ventures encourages broad use of the reSOURCE dataset consistent with a responsible approach to management of intellectual property derived from downstream discoveries.

Additional Ventures considers these data as pre-competitive and urges **Approved Users** to avoid making IP claims derived directly from the dataset(s). It is expected that the reSOURCE dataset, and conclusions derived therefrom, will remain freely available, without requirement for licensing. However, Additional Ventures also recognizes the importance of intellectual property in promoting the development of new therapies and products; as such, there is no restriction on development of commercial products resulting from the knowledge gained from the research project. Ownership of all intellectual property generated by activities under the research project will be governed by applicable patent law.

Disclaimer

THE DATASET AND THE PLATFORM AND ALL RELATED SERVICES THROUGH WHICH THE DATASET IS HOSTED OR ACCESSED, ARE PROVIDED “AS IS” AND “AS AVAILABLE.” ADDITIONAL VENTURES

MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, WITH RESPECT TO THE DATASET, THE PLATFORM, OR ANY SUCH RELATED SERVICES. WITHOUT LIMITING THE FOREGOING, ADDITIONAL VENTURES DOES NOT REPRESENT OR WARRANT (A) THAT THE USE OF THE DATASET, INCLUDING ANY DATA DERIVED THEREFROM, WILL NOT INFRINGE OR MISAPPROPRIATE ANY PATENT OR OTHER INTELLECTUAL PROPERTY OR PROPRIETARY RIGHT OF ANY THIRD PARTY; (B) THE ACCURACY, COMPLETENESS, TIMELINESS, OR PERFORMANCE OF THE DATASET; OR (C) THAT THE PLATFORM OR RELATED SERVICES WILL BE OPERABLE, RELIABLE, SECURE, ERROR-FREE, OR AVAILABLE AT ANY PARTICULAR TIME OR LOCATION, OR THAT ACCESS TO THE DATASET OR THE PLATFORM WILL BE UNINTERRUPTED, CONTINUOUS, OR FREE FROM DELAYS, OUTAGES, DEFECTS, OR HARMFUL COMPONENTS. ADDITIONAL VENTURES DOES NOT WARRANT THAT THE PLATFORM WILL BE COMPATIBLE WITH ANY PARTICULAR HARDWARE, SOFTWARE, SYSTEM, OR USER CONFIGURATION. REQUESTER ACKNOWLEDGES THAT THE PLATFORM MAY BE SUBJECT TO LIMITATIONS, DELAYS, AND OTHER PROBLEMS INHERENT IN THE USE OF ELECTRONIC COMMUNICATIONS AND INTERNET-BASED SYSTEMS. ADDITIONAL VENTURES EXPRESSLY DISCLAIMS ALL WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT, AND ALL WARRANTIES ARISING FROM COURSE OF DEALING, COURSE OF PERFORMANCE, OR USAGE OF TRADE, WITH RESPECT TO THE DATASET, THE PLATFORM, AND ANY RELATED SERVICES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, REQUESTER ASSUMES ALL RISKS ARISING FROM OR RELATING TO ITS USE OF THE DATASET AND THE PLATFORM.

8. Publication; Acknowledgements

Publication

It is Additional Ventures' intent to promote the dissemination of research findings of each Project from use of the Dataset as widely as possible through scientific publication or other appropriate public dissemination mechanisms. The Primary Approved User and all Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings. All IP filings, publications, presentations, or derived works using the Dataset and/or any Derived Data must acknowledge Additional Ventures and the Study as specified in this Section 8. In no event shall such filings or publications include individual-level results or findings that could enable re-identification.

Acknowledgements

The Primary Approved User and all Approved Users shall acknowledge Additional Ventures and the Study (using its full protocol title), in all oral and written presentations, disclosures, and publications, and the like ("**Publications**") resulting from any analyses of the Dataset. The Primary Approved User and all Approved Users shall include the following acknowledgment in all such Publications:

The results analyzed and published here are based in whole or in part upon data generated by Single Ventricle SOURCE, www.svsources.org, accessed from the reSOURCE dataset [Dataset version], funded by Additional Ventures, www.additionalventures.org.

9. Publicity; Use of Name

Publicity

Requester and the Primary Approved User agree that information about themselves, Approved Users, and each Project may be posted publicly by Additional Ventures. Such information may include the name of Requester, the Primary Approved User and all Approved Users, the title of the applicable Project, the Research Use Statement, and a non-technical summary of the Research Use Statement. Citations of publications resulting from the use of the Dataset may also be posted publicly by Additional Ventures. Nothing in this Agreement is intended to restrict a party from disclosing the existence and nature of this Agreement (including the name of the other parties) or from including the existence and nature of this Agreement in the routine reporting of such party's activities.

Use of Name

Neither party will use the name or trademark of the other party, or the names of the other party's employees, students or agents in any publicity, advertising or announcement related to this Agreement without the prior written consent of the other party's authorized officials. Any use of a party's name will be limited to statements of fact and will not imply endorsement by one party of the other's products or services.

10. Liability

Requester shall be responsible for its own acts or omissions and those of its directors, trustees, officers, employees, contractors, agents, representatives, the Primary Approved User, and all Approved Users (each, a "**Representative**") in carrying out each Project and otherwise while exercising their respective rights and performing their obligations under this Agreement, to the full extent allowed by applicable law and regulations. Requester acknowledges that Additional Ventures has no responsibility or liability whatsoever for any Project or Requester's or any Representative's acts or omissions in the conduct of any aspect of a Project, except to the extent any related claims or liabilities arise from the willful misconduct or gross negligence of Additional Ventures.

11. Termination; Retained Data; Survival

Term & Termination

This Agreement is effective as of the Effective Date and remains in effect until terminated by:

- either Additional Ventures or Requester upon thirty (30) days' written notice; or
- Additional Ventures for any material breach of the terms and conditions of this Agreement by Requester and/or the Primary Approved User that is not cured within ten (10) days of notice to Requester of such breach (each, a "**Termination Event**").

Upon the occurrence of a Termination Event, Additional Ventures may immediately revoke or suspend access to the Platform and the Dataset, and the Access Period for each Project then in effect shall terminate concurrently with such Termination Event.

Effect of Termination

Upon termination, all copies of the Dataset and any Individual-level Data must be destroyed by Requester, the Primary Approved User, and all Approved Users, except for any Retained Data

permitted under this Agreement.

A Project Close-out must be completed when a DAC-approved Project is completed. Upon Project Close-out, Requester and the Primary Approved User shall destroy and ensure the destruction of all copies, versions, and the like, of the Dataset retrieved from the Platform, on both local servers and hardware, and if Cloud Computing was used, delete the data and cloud images from the Cloud Computing provider's storage, virtual and physical machines, and databases. However, Requester and the Primary Approved User may retain encrypted copies of the minimum data necessary for Requester to comply with institutional scientific data retention policy, applicable law, and scientific transparency expectations for disseminated Publications, and/or journal policies ("**Retained Data**"). Requester may retain Derived Data and research outputs that do not include Individual-level Data and do not reasonably enable re-identification, subject to the terms of this Agreement. Any Derived Data containing Individual-level Data shall be subject to the same destruction and limited retention requirements applicable to the Dataset under this Section 11.

Retained Data

If Requester and the Primary Approved User retain any Retained Data or Derived Data, they shall continue to be a steward of such data and are responsible for the management of such data in accordance with this Agreement, any institutional policies, and applicable laws and regulations. Any such Retained Data may be used by Requester and its Approved Users and the Primary Approved User only to support the findings (e.g., validation) resulting from a Project. Derived Data and research outputs that do not include Individual-level Data and do not reasonably enable re-identification may also be used to answer any additional research questions within the scope of the DAC-approved DAR. Research uses outside the scope of the DAC-approved DAR require submission of a new DAR and approval by the DAC.

Survival

Expiration of any applicable Access Period, or termination of this Agreement shall not affect the rights and obligations of a party that accrued prior to such expiration or termination. The provisions of Sections 3-18 inclusive of this Agreement, as well as any other provisions that by their nature or express terms extend beyond termination, shall survive such expiration or termination. In addition, Section 2 will survive solely to the extent necessary to enforce restrictions on use, sharing/redistribution, and Approved Users with respect to any Dataset, Individual-level Data, or Retained Data downloaded, retained, or otherwise maintained outside the platform.

12. Relationship of Parties

Nothing in this Agreement is intended, and shall not be deemed, to create an employment, consulting, agency, partnership, or joint venture relationship among the parties.

13. Severability; Waiver

The provisions of this Agreement are severable, and the unenforceability of any provision hereof shall not affect the enforceability of the remainder of this Agreement. No failure or delay on the

part of a party in the exercise of any right hereunder shall operate as a waiver thereof in that or any future circumstance. No single or partial exercise of any right hereunder shall operate as a waiver of such right or any other right. No waiver shall be effective unless in writing and signed by the waiving party.

14. Cumulative Remedies

All rights and remedies provided herein are cumulative and in addition to, and not in lieu of, any other right or remedy now or hereafter available at law or in equity. Neither asserting a right nor employing a remedy shall preclude the concurrent assertion of any other right or remedy.

15. Notices

Any notices required or permitted to be given under this Agreement shall be given in writing and sent to each party via email. Notices to Additional Ventures shall be sent to Courtney Steger at contact@svsource.org; notices to Requester and the Primary Approved User shall be sent to the email addresses provided in the applicable DAR and the signature lines below. Notices shall be deemed given when received.

16. Assignment

This Agreement shall be binding upon and inure to the benefit of the parties, and their respective heirs, successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party.

17. Entire Agreement; Amendment

This Agreement constitutes the entire and only agreement among the parties relating to each Project, including access to the Platform and use of and access to the Dataset, and all prior negotiations, representations, agreements, and understandings among the parties with respect to the subject matter herein are superseded hereby. Except for changes to Approved Users made in accordance with Appendix A, any amendment of this Agreement must be in a written document that specifically references this Agreement and is signed by a duly authorized representative of each party.

18. Interpretation

For purposes of this Agreement the words “include,” “includes,” and “including” will be deemed to be followed by the words “without limitation”. The headings in this Agreement are inserted for convenience only and shall not constitute a part of this Agreement or be used to construe or interpret any of its provisions.

19. Definitions

(a) **Approved Users:** Individuals authorized to access and use the Dataset for an approved Project,

including employees, trainees, students, contractors, and collaborators affiliated with the Requester or other institutions who (i) are specifically identified in Appendix A, (ii) have been made aware of and agree to comply with the terms and conditions of this Agreement, and (iii) are acting under the oversight of the Primary Approved User. Requester and the Primary Approved User shall remain responsible for ensuring that all Approved Users, including those affiliated with other institutions, comply with the terms and conditions of this Agreement.

- (b) **Cloud Computing:** NIST defines cloud computing as a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. For more information see NIST Special Publication 800-145 ("**NIST SP 800-145**").²
- (c) **Cloud Service Provider (CSP):** A company or institution that offers some component of Cloud Computing to other businesses or individuals, typically Infrastructure as a Service (IaaS), Software as a Service (SaaS) or Platform as a Service (PaaS), as defined in NIST SP 800-145.
- (d) **Derived Data:** Data generated or created by Requester or any Approved User through the processing, filtering, annotation, analysis, transformation, or other use of the Dataset, including modified datasets, variant callsets, annotations, and other computational outputs. Derived Data may include Individual-level Data and shall remain subject to the applicable access, use, confidentiality, and security requirements of this Agreement. Derived Data does not include the Dataset itself.
- (e) **Individual-level Data:** Any data from or derived from the Dataset that are maintained in participant-level form, including individual genomic or clinical records, participant-level extracts, and modified or annotated participant-level datasets, whether or not directly identifying. Individual-level Data excludes aggregate statistics and other non-participant-level outputs that do not reasonably enable re-identification.
- (f) **Information Technology Director:** An Approved User who is generally a senior IT official of Requester with the necessary expertise and authority to affirm the IT capacities of Requester. Such individual is expected to have the authority and capacity to ensure Requester's IT security requirements and policies are followed by all of Requester's Approved Users and the Primary Approved User.
- (g) **IP Rights:** IP rights related to patents, copyrights, moral rights, trade secrets, trademarks, trade dress, industrial designs, mask works, database rights, and all other rights and protections or other intellectual or industrial property of any kind, including without limitation, all registrations and applications for registration and extensions and renewals thereof, of any of the foregoing, anywhere in the world.
- (h) **Non-US Requirements:** ISO/IEC 27001:2022 "Information security, cybersecurity and privacy protection – information security management systems – Requirements"³ and ISO/IEC 27002:2022 "Information security, cybersecurity and privacy protection – Information security controls".⁴

² NIST SP 800-145, The NIST Definition of Cloud Computing | Computer Security Resource Center (CSRC)

³ ISO/IEC 27001:2022 - Information security management systems

⁴ ISO/IEC 27002:2022 - Information security, cybersecurity and privacy protection — Information security controls

- (i) **Primary Approved User:** Employee of the Requester who is a qualified researcher and will oversee research conducted under the DAR.
- (j) **Progress Update:** Information included with an annual DAR renewal or Project Close-out summarizing the analysis of the Dataset obtained through the applicable DAR(s) and any publications and presentations derived from each Project.
- (k) **Project Close-out:** Termination of a Project that used the Dataset and confirmation of (i) destruction of all copies of the Dataset and Individual-level Data other than Retained Data and (ii) retention, if any, of Retained Data and/or Derived Data only as permitted under Section 11.
- (l) **Project Renewal:** Renewal of the Primary Approved User's access to the Dataset for a previously approved Project.
- (m) **Public AI Tool:** Any artificial intelligence tool, service, or model offered for use by the general public, or any third-party AI service that (i) uses customer inputs to train, fine-tune, or improve models by default, or (ii) does not provide contractually enforceable commitments that customer inputs will not be used to train or improve models and will be protected with security measures no less protective than those required under this Agreement.
- (n) **Retained Data:** Encrypted copies of the minimum portion of the Dataset and/or Individual-level Data permitted to be retained under Section 11 for compliance with institutional retention policies, applicable law, and/or to support scientific transparency and reproducibility for disseminated Publications.
- (o) **Third-party IT system:** A collection of computing and/or communications components and other resources that support one or more functional objectives of an organization.

Additional Ventures looks forward to working with Requester and the Primary Approved User to advance innovative research to solve SVHD and related conditions.

Very Truly Yours,

Kirstie Keller, PhD
Chief Executive Officer, Additional Ventures Foundation

Requester Acknowledgement:

By signing below, the signer acknowledges having read and agrees to be bound by the terms and conditions of this Agreement as of the Effective Date. Signer also represents that they have the authority to execute this Agreement on behalf of the Requester and to bind the Requester to its terms.

Institutional/Organizational Business Official Signature

On behalf of: _____
[Name of Institution]

Signature: _____

Print Name: _____

Title: _____

Email: _____

Date: _____

Primary Approved User Acknowledgement:

By signing below, the signer acknowledges that they have read this Agreement in its entirety, understand its contents, and acknowledge their obligations hereunder. The signer also acknowledges that they are the researcher who will oversee research under this DAR.

Signature: _____

Print Name: _____

Title: _____

Email: _____

Date: _____

Appendix A: Approved Users

This Appendix A is incorporated into and made part of the SOURCE Data Use Certification Agreement (“Agreement”) between Additional Ventures and the Requester. Only individuals listed in Appendix A are authorized to access the Platform and/or Dataset under the Agreement.

Role	Name	Title	Institution	Email	Date Added
Primary Approved User					
Approved User					
Approved User					
Approved User					
Approved User					
Approved User					
Approved User					
Approved User					

Instructions:

List the name, title, institution, and email address for every individual who will access the reSOURCE dataset as part of this project, including the principal investigator, co-investigators, analysts, trainees/students, external collaborators, and any other team members who will access the data or workspace. Access is granted on a named-user basis and is limited to approved individuals listed in this Appendix A.

Changes to Approved Users

The Primary Approved User may request additions, removals, or updates to the information of Approved Users by written notice to Additional Ventures, including by email. Such changes shall become effective only upon written approval by Additional Ventures, which may also be provided by email. Changes approved through this process shall be incorporated into Appendix A without requiring a formal amendment to the Agreement or additional signatures, provided that no other terms of the Agreement are modified.

Primary Approved User Acknowledgement:

By signing below, the signer confirms that this Approved Users list is accurate and that no additional individuals will access the Platform/Dataset unless an update to Appendix A is submitted to Additional Ventures for review and is approved.

Signature: _____

Print Name:

Date: _____