



PRIMED
consortium

PRIMED Consortium Data Sharing Agreement

Date Approved: November 15, 2023

Date of Last Update: November 2, 2023

Version: 3.0

Introduction

The name of the data sharing group is the PRIMED Consortium Data Sharing Agreement Group (PRIMED-SAG). Members of the PRIMED-SAG must agree to follow the policies and principles set out by the PRIMED Consortium. Additional members of the PRIMED-SAG are likely to join over time. The PRIMED Consortium has developed policies for collaborations, publications, and data sharing. The key documents are:

- [PRIMED Code of Conduct](#): Provides a description of a set of values, rules, standards, and principles outlining what PRIMED Consortium members can expect from staff within an organization.
- [PRIMED Publications Policy](#): Principles to create transparency, foster collaboration, and ensure timely sharing of paper proposals and products within the PRIMED Consortium.
- [PRIMED Data Sharing Policy](#): Processes and procedures to facilitate the access, sharing, and broad usage of data across the PRIMED Consortium, designed to promote scientific efficiency and collaboration while protecting study participants' privacy and respecting consent.

Additional Consortium policies will be added to the [Policies](#) section of the public-facing website as they are approved and adopted by the PRIMED Steering Committee.

PRIMED-SAG WEBPAGE:

To avoid repeated revisions of this Data Sharing Agreement, updated lists of parties to the Agreement (see [Definitions section](#) for types of parties), authorized accounts, studies, consent groups, and secure data location site(s) are maintained at the **PRIMED-SAG webpage**:

<https://primedconsortium.org/research/primed-sag>

A brief description of the PRIMED-SAG's purpose.

The NIH-funded [Polygenic Risk Methods in Diverse Populations \(PRIMED\) Consortium](#) is developing and evaluating methods to improve the use of polygenic risk scores (PRS) to predict disease and health outcomes in diverse ancestry populations. The purpose of the PRIMED-SAG is to enable collaboration and collaborative analyses within the PRIMED Consortium by bringing together large datasets with genomic and health measures from diverse ancestry populations. This Agreement will facilitate the sharing of data in the PRIMED-SAG.

A description of the structure of the PRIMED-SAG.

The PRIMED Study Sites and Coordinating Center are voting parties to this Agreement and are defined as "MEMBERS". For each MEMBER, the contact PI's institution is a signatory on the CDSA for the given MEMBER. For multi-institution MEMBERS, each additional institution (for multiple PIs) is a signatory on the CDSA as a MEMBER COMPONENT (see Definitions).

MEMBERS include:

1. [CAPE](#) (Center for Admixed Populations and Health Equity)
2. [CARDINAL](#) (CARdiometabolic Disorders IN African-ancestry popuLations)
3. [D-PRISM](#) (Diabetes Polygenic Risk Scores in Multiple ancestries)
4. [EPIC-PRS](#) (EndoPhenotype InCorporated PRS)
5. [FFAIRR-PRS](#) (Functional and Fine-Mapping Approach to Improve Responsible Risk-modeling of Polygenic Risk Scores)
6. [PREVENT](#) (Polygenic Risk Estimation and Validation to ENhance Treatment - Coronary Heart Disease)
7. [PRIMED-Cancer](#) (Leveraging Diversity in Cancer Epidemiology Cohorts and Novel Methods to Improve Polygenic Risk Scores)
8. [Coordinating Center](#) (CC)

The PRIMED-SAG is guided by the PRIMED [Steering Committee](#), which includes one voting representative for each MEMBER.

A description of the structure of the PRIMED-SAG.

Over time, with PRIMED Steering Committee approval, PRIMED Affiliate Members can join the PRIMED-SAG as DATA AFFILIATES (studies or consortia contributing data for use by the PRIMED-SAG) or NON-DATA AFFILIATES (centers that develop methods or analyze PRIMED-SAG Data) who agree to participate and abide by this Agreement.

COMPONENTS (associated centers or institutions who wish to use SAG Data) can join the PRIMED-SAG if they are represented by and have a relationship to their respective MEMBER, DATA AFFILIATE, or NON-DATA AFFILIATE.

Each MEMBER, DATA AFFILIATE, NON-DATA AFFILIATE, and their COMPONENTS must submit a copy of the signed and executed Consortium Data Sharing Agreement (CDSA) to the PRIMED CC. The PRIMED Consortium will work with non-US DATA AFFILIATES to try and facilitate data sharing according to regulations.

The PRIMED Steering Committee must approve new DATA AFFILIATES and NON-DATA AFFILIATES (but not their respective COMPONENTS) to participate in the PRIMED-SAG. MEMBER COMPONENTS also do not require PRIMED Steering Committee approval to join the PRIMED-SAG.

The PRIMED-SAG will consist of those who have submitted their copy of the signed and executed CDSA to the CC.

The PRIMED-SAG WEBPAGE maintains a complete list of signatories (MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, and COMPONENTS) who will have access to PRIMED-SAG Data.

Each signatory party will ensure that its investigator REPRESENTATIVE will maintain a list of individuals approved to access the PRIMED-SAG Data under their fully executed Agreement, and they agree to provide updated lists to the CC and thereby the PRIMED-SAG WEBPAGE. Each signatory party agrees to ensure that its REPRESENTATIVE, investigators, fellows, students, and research staff do not use, disclose or transfer any PRIMED-SAG Data to anyone except as permitted by this Agreement.

Proposal for a CDSA study review process

When a Proposer (see Definitions section) wants to use SAG Data from a study, the study contact (if they opt in) will get an email and will be able to review the proposal (approve/disapprove and leave comments regarding the use of their study's data). This optional measure gives DATA AFFILIATES oversight over how their data is used within the PRIMED-SAG.

Data, secure storage, and plans for sharing in the PRIMED-SAG.

Data security and participant confidentiality are paramount to each of the contributing studies and to the PRIMED-SAG. PRIMED-SAG Data will be stored in the cloud on secure data servers maintained by the NHGRI Genomic Data Science Analysis, Visualization, and Informatics Lab-space ([AnVIL](#)), which provides a secure computing environment for data access and analysis.

Access to PRIMED-SAG Data will be through shared Consortium data storage workspaces in AnVIL. Individuals approved to access the PRIMED-SAG Data (see above) will be granted access to all PRIMED-SAG data storage workspaces. The CC will manage access to PRIMED-SAG data storage workspaces via AnVIL auth domains and user credentials. Access to these data storage workspaces will be limited to the PRIMED-SAG and, potentially, AnVIL staff who may have developer data access for non-research purposes, such as maintaining AnVIL user services.

The CC will maintain a list of PRIMED-SAG data storage workspaces and, if applicable, participant-consent related restrictions on data use for data in each PRIMED-SAG data storage workspace. These will be available via the PRIMED-SAG WEBPAGE.

Importantly, PRIMED-SAG datasets will minimally conform to de-identification standards in accordance with applicable law and the [NIH Genomic Data Sharing \(GDS\) Policy](#). Additional de-identification guidelines and standards may be applied by data contributors, when required by the given source study, cohort, or repository, or their institutional policies.

Individual-level phenotype and genotype data and [genomic summary results](#) (GSR) data are uploaded to PRIMED-SAG data workspaces by DATA AFFILIATES or DATA AFFILIATE COMPONENTS, as designated by each DATA AFFILIATE REPRESENTATIVE. Contributors are responsible for harmonizing and formatting data in accordance with the PRIMED data model established by the consortium. Data elements will need to include any participant-consent related restrictions on the use of the data known to the contributing DATA AFFILIATE or DATA AFFILIATE COMPONENT. Each MEMBER, AFFILIATE, and COMPONENT agree to comply with all limitations accompanying the SAG Data, as described in the [Terms and Conditions 4. Complying with Consents](#).

It is not the purpose of the PRIMED-SAG or its data workspaces to serve as a data distribution hub to the broader scientific community. Rather, it is to create a shared infrastructure to bring data, analysis tools, and investigators together to expedite coordinated analyses and methods development. Accordingly, SAG Data shall remain in the shared cloud infrastructure; copying of SAG Data or download to local systems is **not permitted** under this Agreement. Note that download from these data workspaces can not be technically disabled, but downloading, which may be tracked, or copying of SAG Data to local systems will be considered a breach of this Agreement. Also note that analyses using SAG Data will be performed in MEMBER, AFFILIATE OR COMPONENT owned analysis workspaces, so analysis results (e.g. summary statistics, figures, etc.) will be in those analysis workspaces, from which download of analysis results (but not study data) is allowed.

Access to PRIMED-SAG Data hosted on the cloud service provider is governed by a fully executed PRIMED Consortium Data Sharing Agreement.

PRIMED-SAG must produce and maintain Records, in sufficient detail and in a good scientific manner, all of which must be complete and accurate in all material respects, and which will fully and properly reflect (1) documentation of all work done and all results achieved (e.g. paper proposals, publications, and pre-prints) using SAG Data and (2) steps PRIMED-SAG has taken to secure, use and destroy SAG Data (e.g. tracking of data disposition and data access) - collectively the "**Records**"; see also data disposition as described in Terms 7 and 12. SAG Records does not include SAG Data. PRIMED-SAG must retain such Records for at least five (5) years following the termination or expiration of this Agreement. The location and mechanism of maintaining these Records may differ depending on type (e.g. publications, data disposition, data access and use) and may make use of archival website(s). PRIMED-SAG agrees that MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, and their respective COMPONENTS have the right to inspect and copy such Records at reasonable, mutually agreeable times and on reasonable notice both during the term of this Agreement and the five (5) year period following its termination or expiration. Inspections of such Records will be limited to a maximum

of two (2) representatives from MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, and their respective COMPONENTS for two (2) days per annum.

Definitions

For purposes of this agreement:

1. **PRIMED Consortium Data Sharing Agreement (Agreement or CDSA)** refers to this document.
2. **PRIMED Consortium Data Sharing Agreement Group (PRIMED-SAG or SAG)** refers to the data sharing circle established by signatories (MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, and their respective COMPONENTS) as defined in this PRIMED Consortium Data Sharing Agreement who have submitted their copy of the signed and executed CDSA. PRIMED-SAG signatory parties must agree to follow the principles set out by the PRIMED Consortium.
3. **MEMBER** refers to the **Study Sites and Coordinating Center** funded through the primary PRIMED grant mechanisms whose MEMBER REPRESENTATIVE will sign to acknowledge and their institution will act as signatory to this PRIMED CDSA; see definition of REPRESENTATIVES. MEMBERS (e.g. multi-institutional) may have MEMBER COMPONENTS; see definition of COMPONENTS. MEMBERS are voting parties to this Agreement with each MEMBER having representation on the PRIMED Steering Committee; see definition of PRIMED Steering Committee.
4. **AFFILIATE** refers to non-voting parties to this Agreement, who have been approved to join PRIMED as Affiliate Members, and are additionally approved to participate in the PRIMED-SAG by the PRIMED Steering Committee. Therefore not all PRIMED Consortium Affiliate Members need to become PRIMED-SAG AFFILIATES (see a and b below). The terms of the Affiliate Membership and the process for becoming an Affiliate Member are described in the PRIMED Consortium Affiliate Membership Policy. The AFFILIATE REPRESENTATIVE will sign to acknowledge and their institution will act as signatory to this PRIMED CDSA and is bound to its applicable Terms and Conditions; see definition of REPRESENTATIVES. An AFFILIATE (e.g. multi-institutional) may have AFFILIATE COMPONENTS; see definition of COMPONENTS.
 - a. **DATA AFFILIATE** refers to the parties to this Agreement that are studies/cohorts or consortia contributing data for use by the PRIMED-SAG to carry out the scientific goals of the PRIMED Consortium. A DATA AFFILIATE may be a single or multi-institution study/cohort or a consortium of studies. Note Data Affiliate Members that want to contribute their data to the SAG become DATA AFFILIATE parties to this Agreement.
 - b. **NON-DATA AFFILIATE** refers to the parties to this Agreement that are centers that develop methods and/or conduct analyses of PRIMED-SAG data and who

wish to use SAG Data. Note Expertise Only Affiliate Members who do not wish to use SAG Data would not become NON-DATA AFFILIATE parties to this Agreement.

5. **REPRESENTATIVE** refers to the **investigator** who is representing its MEMBER, AFFILIATE, or COMPONENT in the PRIMED-SAG. Signatures are required from both the investigator REPRESENTATIVE and their institution to allow their MEMBER, AFFILIATE, or COMPONENT to use PRIMED-SAG Data. Each institution agrees to ensure that its REPRESENTATIVE, fellows, students, and research staff do not use, disclose or transfer any PRIMED-SAG Data to anyone except as permitted by this Agreement. The investigators, fellows, students, and research staff are held to all applicable and stated standards herein. The REPRESENTATIVE will maintain a list of individuals approved to access the PRIMED-SAG Data under the institution's executed Agreement, and agree to provide updated lists to the CC. Additionally, the
 - **MEMBER REPRESENTATIVE** or their designee serve in the overseeing body of the PRIMED-SAG, the PRIMED Steering Committee; see definition of PRIMED Steering Committee.
 - **DATA AFFILIATE REPRESENTATIVE** will sign to acknowledge and their institution will act as signatory to the CDSA to bring their study/consortium data into the PRIMED-SAG. The DATA AFFILIATE REPRESENTATIVE will additionally provide a list of designated uploaders who are permitted to upload data from their study/consortium into the PRIMED-SAG data workspaces.
6. **COMPONENT** refers to parties to this Agreement who wish to use SAG Data, and who are associated centers, institutions, or groups that are represented by and must have a relationship to their respective MEMBER, DATA AFFILIATE, or NON-DATA AFFILIATE. Note associated centers of MEMBERS and AFFILIATES who do not wish to use SAG Data would not become COMPONENT parties to this Agreement. The COMPONENT REPRESENTATIVE will sign to acknowledge and their institution will act as signatory to this PRIMED CDSA and is bound to its applicable Terms and Conditions; see definition of REPRESENTATIVES. Additionally, the
 - a. **MEMBER COMPONENT** has voting representation in the PRIMED Steering Committee through their respective MEMBER rather than the MEMBER COMPONENT itself.
 - b. **DATA AFFILIATE COMPONENT** (like their respective DATA AFFILIATE) are non-voting parties to this Agreement.
 - c. **NON-DATA AFFILIATE COMPONENT** (like their respective NON-DATA AFFILIATE) are non-voting parties to this Agreement.
7. **PRIMED Steering Committee** is the overseeing body of the PRIMED-SAG with representation from each MEMBER and must approve new DATA AFFILIATES and

NON-DATA AFFILIATES (but not their respective COMPONENTS) to participate in the PRIMED-SAG. MEMBER COMPONENTS also do not require PRIMED Steering Committee approval to participate in the PRIMED-SAG.

8. **PRIMED-SAG Data (SAG Data)** refers to any individual-level or summary-level data brought into the PRIMED-SAG, and any data that are derived, harmonized, imputed, or re-processed from those data. SAG Data can be used by the PRIMED-SAG and are subject to this Agreement. SAG Data may be combined with non-SAG Data to improve the power for novel genetic discoveries or other advances.
 - a. In the above, “**data**” refers to "Scientific Data" as defined in the [guide to the 2023 NIH Data Management and Sharing Policy](#) - the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.
9. **SAG Records (Records)** refers to (1) documentation that reflect all work done and all results achieved (e.g. paper proposals, publications, and pre-prints) using SAG Data and (2) steps PRIMED-SAG has taken to secure, use and destroy SAG Data (e.g. tracking of data disposition and data access). SAG Records does not include SAG Data.
10. **PRIMED-SAG WEBPAGE** <<https://primedconsortium.org/primed-sag>> maintains and/or links to complete and up-to-date lists of signatory parties (MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, COMPONENTS) and the list of authorized accounts (individuals) associated with each signatory party who will have access to PRIMED-SAG Data. The PRIMED-SAG WEBPAGE will also maintain and/or link to up-to-date lists of the studies and consortia contributing PRIMED-SAG Data, their consent groups, secure data location site(s), and PRIMED-SAG data storage workspaces.
11. **Proposer** refers to any PRIMED Consortium member (or group of members) in the PRIMED-SAG that submits a PRIMED paper or project proposal.
12. **Parties involved in the project** are those institutions identified in the paper or project proposal that will conduct the project or that provide data that will be used in the project.

Agreement

The Institution signing this Agreement shall ensure that all of the users of SAG Data within their MEMBER, AFFILIATE, or COMPONENT agree to abide by the PRIMED Consortium policies and principles incorporated on the first page.

Scope of Work

Please see the [Introduction](#) for an overview of the scope and activities of the PRIMED Consortium. In PRIMED, PRS will be developed across different domains, such as cardiometabolic diseases, cancer, and risk factors for and consequences of these conditions. Investigators are responsible for the development and submission, via a PRIMED paper proposal, of pre-specified analysis plans including specific phenotypes or other variables of interest (including covariates such as demographics and social determinants of health). The paper proposal process is described in the [PRIMED Publications Policy](#). Each approved (multi-site) or registered (single-site) analysis plan is expected to focus on its phenotypes of interest and to respect any and all participant-consent-related limitations on the use of the data. For example, datasets with disease-specific Data Use Limitations will only be used in the development or improvement of PRS for the corresponding disease. Further, study/cohort datasets may or may not be used for each specific proposal, based on participant-consent-related limitations.

Terms and Conditions

1. Sharing among the PRIMED-SAG

The PRIMED-SAG refers to the data sharing circle established by signatories and is composed of MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, and their respective COMPONENTS who agree to share data within the PRIMED-SAG according to PRIMED Consortium policies and this Agreement. The DATA AFFILIATE studies and consortia whose data are to be shared are listed on the PRIMED-SAG WEBPAGE. These data may be shared among the PRIMED SAG according to the Terms and Conditions stated in this Agreement. Sharing for purposes outside the scope of the PRIMED-SAG identified above must receive appropriate permissions from the PRIMED Steering Committee, as long as the PRIMED-SAG is active, and the DATA AFFILIATES that generated the data. The PRIMED-SAG shall be deemed “active” until it is terminated, as described in Term 12.

2. Sharing outside the PRIMED-SAG

As long as the PRIMED-SAG is active, MEMBERS, NON-DATA AFFILIATES, and their respective COMPONENTS agree not to share SAG Data with any party that is not in the PRIMED-SAG, unless the party joins the PRIMED-SAG, agrees to its Terms and Conditions, and signs this Agreement.

As long as the PRIMED-SAG is active, DATA AFFILIATES and their respective COMPONENTS agree not to share SAG Data generated by other DATA AFFILIATES (or their COMPONENTS) with any party that is not in the PRIMED-SAG, unless the party joins the PRIMED-SAG, agrees to its Terms and Conditions, and signs this Agreement.

Principal Investigators at each MEMBER, AFFILIATE, and COMPONENT may work with individuals at their respective institutions as they typically would on research projects. MEMBERS, AFFILIATES, and COMPONENTS may continue to share SAG Data at their respective institutions according to their usual policies, practices, and procedures.

3. Conveying obligations to COMPONENTS

MEMBERS, DATA AFFILIATES, and NON-DATA AFFILIATES consisting of multiple COMPONENTS who wish to use SAG Data agree to have their respective COMPONENTS submit a signed and executed Agreement, so investigators at each COMPONENT use and handle SAG Data according to the provisions of this Agreement and are bound by the Terms of this Agreement. COMPONENTS who have not submitted a signed and executed Agreement to the CC may not share or access SAG Data.

4. Complying with Consents

Each MEMBER, AFFILIATE, and COMPONENT agree to comply with all limitations accompanying the use of the SAG Data contributed by DATA AFFILIATES and their COMPONENTS or their designees (i.e. designated uploaders). DATA AFFILIATES and their COMPONENTS contributing SAG Data will convey all known limitations to the PRIMED CC and PRIMED-SAG, including any constraints on sharing of summary-level data beyond the SAG (e.g., release of single-study or multi-study summary statistics via the GWAS Catalog or sharing of PRS weights and models via the PGS Catalog; note most summary statistics are expected to be multi-study). Limitations should appropriately reflect the data policies of DATA AFFILIATES and the informed consent of Study participants from whom the data shared under this Agreement were collected and derived. Each DATA AFFILIATE, their COMPONENT, or designee will list any known limitations (e.g., Cardiovascular Disease research only, Not-for-profit Use Only) on use of the data it is sharing in the PRIMED-SAG on the PRIMED-SAG WEBPAGE, and, when in doubt about the appropriateness of sharing, will consult with the appropriate ethics board or IRB.

5. Respecting Participant Privacy and Ensuring Data Confidentiality

In order to respect the privacy of the participants from whom data were collected or derived, MEMBERS, AFFILIATES, and COMPONENTS agree not to contact or make any effort to identify individuals, families, communities, tribes, or populations that are or may be the sources of the data. Participant identities may be known to researchers at the DATA AFFILIATE study or consortium that collected the data. But under no circumstances should personally identifying information (e.g., identifiers that qualify as Protected Health Information or as a Limited Data Set under HIPAA) be shared in the PRIMED-SAG. SAG Data are confidential, and breaches to their security may subject MEMBERS, DATA AFFILIATES, NON-DATA AFFILIATES, and/or their respective COMPONENTS to legal action.

6. Publishing and Presenting

The PRIMED Consortium Publications Policy will guide MEMBERS, AFFILIATES, and COMPONENTS in the development and submission of publications and presentations using PRIMED-SAG data.

DATA AFFILIATES, their COMPONENTS, or their designees (i.e. designated uploaders) will provide the PRIMED-SAG with standard acknowledgement language to include in all publications and presentations resulting from membership in the PRIMED-SAG.

7. Withdrawing from the PRIMED-SAG

Any MEMBER, AFFILIATE, or COMPONENT may withdraw from the PRIMED-SAG and terminate their participation in this Agreement at any time by providing the PRIMED Steering Committee via the CC with written notice of its intent to withdraw. If a MEMBER or AFFILIATE withdraws from the PRIMED-SAG, their COMPONENTS, if any, would necessarily also withdraw from the PRIMED-SAG. Following termination, provisions which on their face affect rights and obligations after termination shall survive.

If a DATA AFFILIATE study or consortium withdraws from the PRIMED-SAG, it agrees to work with the PRIMED Steering Committee to handle the disposition of its data (from the DATA AFFILIATE and its COMPONENTS) and the future conduct of studies using its data.

The DATA AFFILIATE will determine an option for disposition after discussion with the PRIMED Steering Committee. Options for disposition of DATA AFFILIATE- or COMPONENT-contributed data after withdrawal of a DATA AFFILIATE include one of the following options:

- Removing the withdrawing DATA AFFILIATE's data (including any DATA-AFFILIATE COMPONENT's data) from the PRIMED-SAG and its workspaces immediately
- Completing current PRIMED-SAG analyses with documented written permission of the withdrawing DATA AFFILIATE or DATA AFFILIATE COMPONENT and not using the withdrawing DATA AFFILIATE's data (including any DATA AFFILIATE COMPONENT's data) for future PRIMED-SAG analyses
- Continuing to use the withdrawing DATA AFFILIATE's data (including any DATA-AFFILIATE COMPONENT's data) with documented written permission of the withdrawing DATA AFFILIATE or DATA AFFILIATE COMPONENT as long as its use is in compliance with all limitations as described in Term 4 and the PRIMED-SAG is active

In addition, the withdrawing DATA AFFILIATE (and its respective COMPONENTS) will abide by PRIMED policy on disposition as outlined herein of PRIMED-SAG Data.

8. Removing a MEMBER, AFFILIATE, or COMPONENT

If any MEMBER, AFFILIATE, or COMPONENT believes that any other MEMBER, AFFILIATE, or COMPONENT is in violation of one or more terms of this Agreement, the MEMBER, AFFILIATE, or COMPONENT who suspects the violation will notify the PRIMED Steering Committee in writing. The PRIMED Steering Committee may determine to notify the offending

MEMBER, AFFILIATE, or COMPONENT of the suspected violation in writing. If the violation is not remedied within 30 days of written notice to the offending MEMBER, AFFILIATE, or COMPONENT, or if a breach of data security or confidentiality is discovered and not remedied within 30 days of notice to the offending MEMBER, AFFILIATE, or COMPONENT, the PRIMED Steering Committee may terminate the offending MEMBER's, AFFILIATE's, or COMPONENT's participation in the PRIMED-SAG and/or the PRIMED Consortium and this Agreement. Once a MEMBER's, AFFILIATE's, or COMPONENT's PRIMED-SAG participation is terminated, COMPONENT withdrawal and data disposition will be handled according to Term 7 as applicable. Following termination, provisions which on their face affect rights and obligations after termination shall survive.

9. No Warranties; Certification

All data shared are provided without warranties, but DATA AFFILIATES and DATA AFFILIATE COMPONENTS each certify to the best of their knowledge and belief that data submitted by it were collected in accordance with all academic laws and academic or industry standards, as applicable, and, for research with human subjects, with the Code of Federal Regulations [45 CFR 46](#) (or with applicable legal and ethical standards, for DATA AFFILIATES based outside the United States).

10. Liability

No indemnification for any loss, claim, damage, or liability is intended or provided by any party to this Agreement. Each MEMBER, AFFILIATE, and COMPONENT shall be responsible for any losses, claims, damages, or liability incurred that directly results from its activities under this Agreement or use of data arising under the Agreement.

11. Data Security

Each MEMBER, AFFILIATE, and COMPONENT signatory party agrees to safeguard SAG Data it accesses as it would its own data. The signatory party shall use all reasonable efforts to keep access to SAG Data secure (including access via a secure cloud-based system) and ensure that no-one other than its REPRESENTATIVE, investigators, fellows, students, and research staff who have a need to have access to the SAG Data for the purposes of the PRIMED Consortium work are provided access under the signatory party's fully executed Agreement. The signatory party shall otherwise share SAG Data as described in Terms 1 and 2.

An updated list of secure data locations is included on the PRIMED-SAG WEBPAGE. Access to PRIMED-SAG Data hosted on the cloud service provider is governed by a fully executed PRIMED Consortium Data Sharing Agreement.

12. Terminating the PRIMED-SAG

This Agreement shall go into effect as of the date both the institutional signatory signs and the investigator REPRESENTATIVE signs to acknowledge and will remain in effect until the PRIMED Steering Committee agrees to dissolve the PRIMED-SAG. The PRIMED Steering Committee will review its progress at the end of the initial funding period to determine whether the activity should continue and whether a new or modified Agreement should be signed.

- When any of the above conditions for termination of the PRIMED-SAG occurs, the SAG members remaining at the time of termination will work together on a plan to:
 - Complete any remaining analyses
 - Destroy data or keep it to share with former SAG members or non-SAG members via DATA AFFILIATE-approved new collaborations or Consortia in accordance with Term 7
 - Upon termination, any remaining DATA AFFILIATE shall be provided with an opportunity to select one of the disposition options provided under Term 7 prior to the implementation of any plan agreed to by the remaining SAG members
- If SAG Data may be used after termination of the PRIMED-SAG, the PRIMED Steering Committee will set conditions for use and will consider issues such as, but not limited to:
 - Whether those outside of the PRIMED-SAG may access SAG Data, and under what circumstances, such as
 - If the non-SAG member collaborates with a former SAG member
 - If other former SAG members are required to agree to the non-SAG member's use, and if so, how many must agree
 - Ensuring that future analyses conform with the original consents
 - Determine whether data may be adapted for use in a repository for long-term access by any qualified researcher without the permission of former SAG members
 - Determine how long into the future former SAG member's input should be required for continued use of SAG Data

13. Intellectual Property

Any intellectual property, including, without limitation, patents, patent applications, software, trademarks, trade names, copyrights, works of authorship, creations and inventions, improvements, proprietary information, data, work product and technology owned by a party prior to or developed by a party independently of this Agreement ("Background IP") will remain the sole property of that respective party. Nothing in this Agreement shall be deemed or construed as a license or grant of any Background IP, unless otherwise expressly stated herein, by one party to another party.

If a Proposer identifies that its Background IP is necessary to perform the approved project, such Background IP shall be described in detail. In such instances, the Proposer hereby grants Parties involved in the project the right to practice such Proposer's Background IP for internal non-commercial research and educational purposes related to the project. See Definitions section for definitions of "Proposer" and "Parties involved in the project."

"Invention" shall mean any patentable invention or discovery that is conceived and reduced to practice in the performance of the project.

"Software" means any copyrightable computer programs and the related documentation and/or specifications and derivative works thereof, including source code and object code forms thereof, as the context indicates, created or authored in the performance of the approved project in accordance with this Agreement.

The Proposer and the Parties involved in the project must promptly disclose any patentable Invention or Software made in performance of the approved project under this Agreement or utilizing contributed SAG Data to the other applicable Parties involved in the project and PRIMED Coordinating Center (“Intellectual Property”).

“Joint Intellectual Property” means Intellectual Property or Software (i) for which one or more inventor(s) is/are member(s) of the Parties involved in the project and one or more inventor(s) is/are members of the Proposer team or other Parties involved in the project, or (ii) for which one of the Parties involved in the project that gave rise to the Intellectual Property or Software provided data used in the project.

Inventorship of Inventions shall be determined in accordance with United States patent law and is subject to the provisions of 37 CFR §401, et. seq., including, but not limited to, applicable government march-in-rights.

Authorship of Software shall be determined in accordance with United States copyright law.

Except as otherwise provided herein, right, title, and interest to any Inventions or Software made solely by a party will vest with that party.

For any Invention or Software meeting the definition of Joint Intellectual Property, the Proposer and the applicable Parties involved in the project will mutually agree in writing to the management of such Joint Intellectual Property. Each Joint Intellectual Property owner shall grant the other Joint Intellectual Property Owners an irrevocable, world-wide, royalty-free, non-exclusive, license to practice any Joint Intellectual Property developed under the applicable project for internal non-commercial research and educational related purposes.

Signatures

1. Name of group affiliation - e.g., CARDINAL, PRIMED CC, DATA AFFILIATE study/consortium (MESA, SiGN), NON-DATA AFFILIATE center (Univ of ABC, Genetic Analysis Center)

2. Institutional signatory represents (check one)

- MEMBER - e.g., PRIMED Study Site (Contact PI), PRIMED CC
- MEMBER COMPONENT - e.g., PRIMED Study Site (co-PI, co-I)
- DATA AFFILIATE - study DCC or other study representative who is responsible for bringing study/consortium data into the SAG (e.g. PRIMED Affiliate Member - Data Affiliate tier)
- DATA AFFILIATE COMPONENT - associated center or group of DATA AFFILIATE (e.g., a study field center or study analysis center)
- NON-DATA AFFILIATE - centers that develop methods or analyze SAG Data (e.g., PRIMED Affiliate Member - Expertise only tier)
- NON-DATA AFFILIATE COMPONENT - associated center or group of NON-DATA AFFILIATE

3. *Respond only if you checked DATA AFFILIATE COMPONENT or NON-DATA AFFILIATE COMPONENT in Question 2:*

Name or description of the relationship of the COMPONENT to its associated group named in Question 1 (e.g. MESA Field Center UCLA, MESA Analysis Center UVA).

4. Name of signing institution.

5. For DATA AFFILIATES and DATA AFFILIATE COMPONENTS only, *optionally*, please indicate if there are any limitations or constraints to the study/consortium data to be shared with the PRIMED-SAG beyond Term 4 (e.g. "genomic summary results only", a list of planned phenotype areas to be shared or to be excluded, etc.)

6. Signatures

The Authorized Official has received authorization for the MEMBER, DATA AFFILIATE, NON-DATA AFFILIATE or COMPONENT REPRESENTATIVE's institution (identified below) to sign on their behalf.

Additionally, for DATA AFFILIATES:

The DATA AFFILIATE REPRESENTATIVE has received authorization from its Study/Consortium to join the PRIMED-SAG. Each DATA AFFILIATE certifies that it authorizes its Study/Consortium data to be shared within the PRIMED-SAG. The DATA AFFILIATE REPRESENTATIVE will provide a list of designated uploaders who are permitted to upload data from their study/consortium into the PRIMED-SAG data workspaces.

Electronic signatures may count as originals.

Executed by:

X _____
Institution's Authorized Official - Signature

Institution's Authorized Official - Name

Institution's Authorized Official - Title

Date

Read and understood by:

X _____
Investigator REPRESENTATIVE - Signature

Investigator REPRESENTATIVE - Name

Investigator REPRESENTATIVE - Title

Date

Change Log

- V3.0
 - November 16, 2023: Added protections or specifications around data contributions for DATA AFFILIATES, aligned terms and definitions, and added clarifications as described in the [PRIMED Consortium Data Sharing Agreement Amendment to CDSA V2.1 to align with V3.0](#).
- V2.1
 - May 31, 2023: Minor clarification in [Introduction](#) on the scope and contents of the PRIMED Code of Conduct.
- V2.0
 - June 14, 2023: Approved by the PRIMED Steering Committee.
 - April 21, 2023: Clarification that the IP terms in Section 13 apply to all parties to the agreement versus limited to DATA AFFILIATES.
- V1.0
 - March 27, 2023: Added/confirmed URLs for the PRIMED-SAG WEBSITE and Data Sharing Policy; Substituted phrase "Proposer or PRIMED-SAG" with defined term "Proposer" as discussed at 3/15/23 Steering Committee meeting.
 - March 15, 2023: The Steering Committee approved the PRIMED Consortium Data Sharing Agreement to be shared with institutions for signing.
 - Initial Agreement adapted from CHARGE Analysis Commons CDSA (Jan 25, 2022), source: <https://www.chargeconsortium.com/commons>
 - CHARGE Analysis Commons CDSA was developed from the NHLBI template, version Aug 23, 2013.