



**PRIMED**  
consortium

## PRIMED Consortium Data Sharing Agreement Amendment to CDSA V2.1 to align with V3.0

*Date Approved:* November 15, 2023

*Date of Last Update:* November 2, 2023

*Version:* 1.0

To: PRIMED-SAG signees that Executed Version 2.1 of the PRIMED Consortium Data Sharing Agreement

From: PRIMED Data Sharing Working Group

Re: Amendment to Version 2.1 of the PRIMED Consortium Data Sharing Agreement, to Align with Version 3.0

Date: November 16, 2023

Dear PRIMED-SAG signee:

Your institution has previously executed version 2.1 of the PRIMED Consortium Data Sharing Agreement (CDSA). The CDSA was revised on November 15, 2023 to version 3.0 ("Version 3.0 Effective Date"). Version 3.0 incorporates the following **edits**, grouped into five categories and referring to page numbers in the CDSA version 3.0:

### **Added protections or specifications around data contributions by DATA AFFILIATES**

- *Addition of phrase (top p.4):* Importantly, PRIMED-SAG datasets will minimally conform to de-identification standards in **accordance with applicable law and** the [NIH Genomic Data Sharing \(GDS\) Policy](#).
- *Addition of optional open text box question (p.15, Signatures section) allowing a DATA AFFILIATE to specify limitations/constraints to what they can bring/share with the PRIMED-SAG beyond what protections are already covered in Term 4 on p.9. This question appears also as Question 5 on p.5 of this Amendment (for those who will instead sign this Amendment to align with CDSA V3.0):*

**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.)**

### Alignment of terms and definitions

- *Replacement of phrase (top p.4):* Individual-level phenotype and genotype data and [genomic summary results](#) (GSR) data are uploaded to PRIMED-SAG data workspaces by a ~~MEMBER, AFFILIATE, or COMPONENT~~ **DATA AFFILIATES or DATA AFFILIATE COMPONENTS**, as designated by each DATA AFFILIATE REPRESENTATIVE.
- *Replacement of phrase (middle p.4):* Also note that analyses using SAG Data will be performed in **MEMBER, AFFILIATE OR COMPONENT** ~~investigator~~-owned analysis workspaces [...]
- *Replacement of phrase (top p.8):* **The Institution signing this Agreement shall ensure that all of the users of SAG Data within their MEMBER, AFFILIATE, or COMPONENT** ~~All users of SAG Data~~ agree to abide by the PRIMED Consortium policies and principles incorporated on the first page.

### Clarification on applicability of existing Consortium policies

- *Clarification (top p.10, Term 6):* The PRIMED Consortium Publications Policy will guide **MEMBERS, AFFILIATES, and COMPONENTS** in the development and submission of the ~~PRIMED-SAG~~ publications and presentations **using PRIMED-SAG data.** *[insert paragraph break]*

### Clarification of Agreement withdrawal and removal policies

- *Addition of phrase/sentence (top p.10, Term 7):* Any MEMBER, AFFILIATE, or COMPONENT may withdraw from the PRIMED-SAG **and terminate their participation in this Agreement** at any time [...]. **Following termination, provisions which on their face affect rights and obligations after termination shall survive.**
- *Addition of phrase/sentence (top p.11, Term 8):* [...] 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.** [...] **Following termination, provisions which on their face affect rights and obligations after termination shall survive.**

### Clarification of IP terms

- *Addition of phrase (bottom p.12, Term 13):* 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.**
- *Addition of word (bottom p.13, Term 13):* 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.

This letter serves as notice that your institution's CDSA is revised to incorporate the change above as of the Version 3.0 Effective Date.

If you have any questions regarding this letter, please contact the PRIMED CC <primedconsortium@uw.edu> and Data Sharing WG co-chairs Whitney Hornsby and Yuji Zhang <whornsby@mgh.harvard.edu, yuzhang@som.umaryland.edu>.

Please **return** your fully executed Amendment letter to the **PRIMED CC (primedconsortium@uw.edu)** to indicate your institution's acknowledgement and acceptance of this change.

Sincerely



Whitney Hornsby (FFAIRR-PRS, Massachusetts General Hospital)  
Yuji Zhang (CARDINAL, University of Maryland Baltimore)  
(Data Sharing Working Group Co-Chairs)

## Signatures

*Please complete Questions 1-4 in the same manner as in your fully executed V2.1 PRIMED CDSA so this Amendment letter can be mapped to your V2.1 CDSA. Exception: for those who had correspondence with the PRIMED CC to update/correct the responses to Questions 1-4, please use the agreed upon updates.*

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)

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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).

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4. Name of signing institution.

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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.

*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