

CHS DMDA INSTRUCTIONS

Access to individual, participant level (raw) data and/or original materials requires a DMDA completed as instructed below.

Completing the DMDA:

Note: You may prepare and submit more than one original DMDA if you would like us to return a hardcopy to you for your files. (The completed agreement may also be scanned and emailed to you).

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| Section 1 “Materials:” | Please generally describe what is more explicitly specified in the approved Research Project. (If Research Project involves data only, please enter “n/a” or leave blank). |
| Section 2 “Data:” | This agreement covers only data described in the approved Research Project. Investigators should state in broad terms the kind of data they’re requesting according to their overall area of research interest. |
| Section 3.1 “Research Project:” | (Title of the approved study proposal or paper proposal) |
| Section 3.2 “Other Recipients:” | For additional outsourced/contracted recipient only, as defined in section 4.2. |
| *Section 18 “IRB” / Ethics Review: | Attach photocopy or scan of the current Recipient Institutional IRB review letter associated with the Research Project. |
| Sign. 1 “Recipient’s PI:” | Principal Investigator (PI). Data/materials will be transferred only to PI, who assumes responsibility for students/staff participating in the Research Project (DMDA clause 5). <u>Please notify the Coordinating Center with the names of any additional persons who will receive access (eg, author or analyst on a paper).</u> |
| Sign. 2 “Recip.’s Authorized Rep:” | Recipient Institution (usually Business Office, Office of Research, Licensing & Technology, or Grants & Contracts - the signer must have local institutional authority to legally commit the institution to this agreement.) <i>University of Washington Recipients: please include evidence of Research Project (proposal) approval when forwarding your DMDA to the UW Office of Sponsored Programs (OSP) for this signature. Send either hardcopy or emailed scan of both documents to OSP Box 359472 / osp@uw.edu.</i> |
| Sign. 3 “CHS CC:” | Completed by CHSCC following signatures 1 & 2. |
| Sign. 4 “NHLBI Rep.:” | [Materials only] Obtained by CHSCC following signatures 1 & 2. |

*IRB REVIEW (DMDA Clause #18):

This DMDA must include current evidence of review by your institution’s Institutional Review Board (IRB). IRB review may be “exempted,” “expedited,” or “full.” Data and/or materials approved for transfer will contain no personal identifiers per current HIPAA regulations. However, a slight possibility remains that individual participants could be identified, if only because of the sheer volume of data or because of other data such as outliers, dates, and study sites. Access to data and/or material containing personal identifiers may not be exempted from IRB review.

Please send to:

Lisa Muth, Research Administrator
 Collaborative Health Studies Coordinating Center
 Building 29 Suite 210, University of Washington,
 Box 354922 6200 NE 74th Street, Seattle, WA 98115
 Phone: (206) 897-1912 / Email: lmuth@uw.edu