

## Appendix R

### Guidelines for Collaborative Studies Using PRAMS Data & Data Sharing Agreements

There are numerous opportunities for PRAMS states to conduct collaborative analyses with other PRAMS states and CDC. There is also interest from researchers external to both CDC and the states in conducting analyses with PRAMS data, often by combining the data from multiple states. To facilitate these collaborative efforts, various data sharing agreements have been created (refer to accompanying pages). These agreements were written to protect the integrity of state data and to promote opportunities for states to comment upon analyses performed by others (e.g. external researchers, other states, CDC) prior to their publication or presentation.

Given the growth in the number of PRAMS sites over the years, CDC coordinates the process for release of multi-state datasets to researchers. CDC worked with The National Association for Public Health Statistics and Information Systems (NAPHSIS) to identify a specific set of birth certificate variables and define the acceptable groupings of these variables for release to researchers by CDC without individual state vital records review. These birth certificate variables are listed in **Section A** of this **Appendix R**. To formalize this agreement, the **Data Sharing Between CDC and Participating PRAMS States** is signed by the state PRAMS program staff member and the state Vital Records representative and submitted to CDC at the beginning of each grant cycle. A list of questionnaire variables was also identified for release to researcher by CDC, and this list is found in **Section B** of this **Appendix R**. Prior to CDC PRAMS releasing data, all researchers must sign the **CDC PRAMS Agreement for Sharing Multi-state Data with External Researchers** and submit it to CDC. Requests from researchers that require birth certificate variables not specified in **Section A**, go directly to each relevant state for approval. A copy of the letter of agreement between CDC PRAMS and NAPHSIS is found in **Section C** of this **Appendix R**.

PRAMS data offer researchers from a variety of health and social science disciplines the opportunity to investigate research questions. As such, researchers who work in a state agency, but are not members of a state's PRAMS Working Group, or researchers who are not aligned with a state agency may request access to PRAMS data. Providing access to PRAMS data to external researchers offers several benefits: data analysis efforts extend beyond persons directly involved with PRAMS, state PRAMS staff gain insight from an external perspective, and dissemination activities are expanded.

Because PRAMS data contain confidential and sensitive information regarding behaviors before, during, and after pregnancy, states are advised to develop a policy for how their PRAMS data will be shared with external researchers, should such a request arise for single state data requests that come directly to the state. To streamline the process, a staff person may be designated to handle such requests and to monitor

adherence to security and confidentiality requirements. The state may also want to keep a log of all data requests and releases. The state PRAMS program should maintain communications with the staff of the Vital Records Department regarding the release of data, as birth certificate variables are included in the PRAMS dataset.

A state policy addressing external researcher requests should describe the following elements:

- The documentation of the proposed research that is required. It should address how the data will be used, any proposed data linkages, the variables to be included, the person responsible for compliance with the agreement, and all collaborators on the project.
- Any limitations on use of data, including prohibition on identifying individuals and linkages without prior permission.
- Procedures for releasing data to other collaborators and ban on releasing data to other parties.
- A signed agreement from the researcher that protects the state against breaches of confidentiality and prevents any potential misuse of the data.
- How the data will be given to the researcher.
- How the state will monitor access given to external researchers and any penalties for breaches in the agreement.
- Security procedures during and after the analysis has been completed.
- What the researcher should do with the data once the analysis has been completed.

States may wish to request that the researcher draft a proposal that summarizes the project. The proposal can be reviewed by state PRAMS staff prior to granting approval for access, and PRAMS staff can provide comments and suggestions given their familiarity of the strengths and limitations of PRAMS data.

States may decide to create a state-specific data sharing agreement, if one is not already available for use from other state programs that already have data release policies in place. States may model their agreement based on the **CDC PRAMS Agreement for Sharing Multi-state Data with External Researchers** or develop an agreement that better suits their needs. The agreement should include:

- Limitations on the use of the data.
- Limitations on data access and a promise not to release it to others.

- An agreement not to try to identify anyone, not to link the data to other datasets without permission, and to notify the state of any inadvertent identification of individuals.
- Requirements for appropriate acknowledgements and review.
- Request to include the keyword “PRAMS” on any journal articles.
- A statement of return or destruction after analysis is completed.
- Procedures for monitoring compliance and penalties for failing to comply.

### **Protocol Development Task**

Develop a policy for granting external researchers access to PRAMS data. This policy should delineate what documentation about the proposed research is necessary, the mechanism for reviewing external data requests, the type(s) of data sharing agreement(s) required, other information needed to deliver the data, the time frame to grant access to the data, and the medium by which the data will be given.

Identify an individual who will be responsible for obtaining completed data sharing agreements from external researchers and monitoring adherence to the agreements.

## **CDC PRAMS AGREEMENT FOR SHARING MULTI-STATE DATA WITH EXTERNAL RESEARCHERS**

I, \_\_\_\_\_, as principal investigator/co-investigator on this proposed analysis of Pregnancy Risk Assessment Monitoring System (PRAMS) data, agree to the following requirements for the use of PRAMS data and assure compliance with the requirements by all staff and collaborators approved as part of this agreement.

1. I will not use these data except for statistical analysis and reporting as described in the attached proposal.
2. I will not use nor permit approved collaborators and staff to use these data to conduct analyses other than those described in the proposal, titled \_\_\_\_\_, which accompanies this statement.
3. I will not release the data set or any part of it to any person other than those listed as collaborators in the attached proposal. I will assure that all approved collaborators understand that they may not share the data set or any part of it.
4. I will not attempt or permit others to use the data set or link it with other data sets to attempt to learn the identity of any participant. If the identity of a respondent should be inadvertently discovered, I will make no use of this knowledge, nor will I permit others to use the knowledge. I will inform the CDC-PRAMS staff of the discovery, so they can prevent future discoveries. I pledge that neither I nor other members of my team will inform anyone else of this knowledge.
5. All oral or written presentations of the results of the analyses will include an acknowledgment of the PRAMS Working Group and the Centers for Disease Control and Prevention.
6. All oral or written presentations of the results of the analyses will be submitted, prior to presentation or submission to a journal, to the Centers for Disease Control and Prevention so that CDC can forward them to the PRAMS participating states for their information. States will have two weeks to submit comments on the presentation/publication to the author.
7. The acronym "PRAMS" will be submitted as a keyword for any publication.
8. CDC PRAMS staff and staff from states whose data were used in the analysis will be notified upon final publication of an article and provided with citation information.
9. When the proposed analyses are completed, all copies of these data will be destroyed (confirmed in writing) or returned to CDC.

My signature and the signatures of all investigators indicate our agreement to comply with these requirements.

Name of principal investigator: \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signatures of collaborators: \_\_\_\_\_

# Data Sharing Agreement between CDC and Participating PRAMS States/Sites

**2011 - 2016**

The PRAMS project in the state/site of \_\_\_\_\_ agrees to allow staff of the Centers for Disease Control and Prevention (CDC) to release the PRAMS Analytic Research File to researchers from **April 15, 2011 to April 14, 2016**.

The PRAMS Analytic Research File includes:

- Birth certificate variables enumerated in Section A;
- Operational, Analytic, and Core Questionnaire variables listed in Section B;
- The file will be customized to include only the states and years of data requested by the researcher;
- Questionnaire variables on state-specific topics (i.e. not core questions, but standard or state-specific questions) will be included if requested and justified by the researcher.

Section B contains Phase 5 variables names; comparable variables from other questionnaire phases are released if requested.

Any researcher requesting birth certificate variables **not** included in the standard PRAMS Analytic Research File, as specified in Section A, will be required to submit a proposal directly to the states of interest, and will need to comply with individual state vital registrar approval processes and IRB requirements. CDC will create the aggregate dataset for such requests only upon the researcher's submission of written approval from each relevant state vital registrar to CDC.

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PRAMS Representative Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Vital Statistics Representative Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Section A. List of Birth Certificate Variables from the 2003 Revised Birth Certificate and Defined Groupings for Release to Researchers by CDC

SEX	Sex	
MM_DOB	Infant Date of Birth - Month	
YY4_DOB	Infant Date of Birth - Year	
POB	Type of Place of Birth	
MAT_AGE	Maternal Age	Grouped: <= 17, 18-19, 20-24, 25-29, 30-34, 35-39, 40+
EVER_MAR	Ever Married	
MARRIED	Married at conception, at birth, or anytime in between	
PAT_ACK	Acknowledgement of Paternity	
MAT_ED	Maternal Years of Education	This variable is grouped
PAT_ED	Paternal Years of Education	This variable is grouped
HISP_BC	Maternal Hispanic Origin	
FHISP_BC	Paternal Hispanic Origin	
MRACE_WHT	Maternal Race - White	
MRACE_BLK	Maternal Race - Black	
MRACE_AMI	Maternal Race - American Indian or Alaska Native	
MRACE_ASI	Maternal Race - Asian Indian	This variable is grouped
MRACE_KOR	Maternal Race - Korean	This variable is grouped
MRACE_VTM	Maternal Race - Vietnamese	This variable is grouped
MRACE_ASO	Maternal Race - Other Asian	This variable is grouped
MRACE_GAM	Maternal Race - Guamanian or Chamorro	This variable is grouped
MRACE_SAM	Maternal Race - Samoan	This variable is grouped
MRACE_PIO	Maternal Race - Other Pacific Islander	This variable is grouped
MRACE_CHN	Maternal Race - Chinese	No grouping for this variable
MRACE_FLP	Maternal Race - Filipino	No grouping for this variable
MRACE_JPN	Maternal Race - Japanese	No grouping for this variable
MRACE_NHW	Maternal Race - Native Hawaiian	No grouping for this variable
MRACE_OTH	Maternal Race - Other	No grouping for this variable
MAT_RACE	Maternal Race	
FRACE_WHT	Paternal Race - White	
FRACE_BLK	Paternal Race - Black	
FRACE_AMI	Paternal Race - American Indian or Alaska Native	
FRACE_ASI	Paternal Race - Asian Indian	This variable is grouped
FRACE_KOR	Paternal Race - Korean	This variable is grouped
FRACE_VTM	Paternal Race - Vietnamese	This variable is grouped
FRACE_ASO	Paternal Race - Other Asian	This variable is grouped

FRACE_GAM	Paternal Race - Guamanian or Chamorro	This variable is grouped
FRACE_SAM	Paternal Race - Samoan	This variable is grouped
FRACE_PIO	Paternal Race - Other Pacific Islander	This variable is grouped
FRACE_CHN	Paternal Race - Chinese	No grouping for this variable
FRACE_FLP	Paternal Race - Filipino	No grouping for this variable
FRACE_JPN	Paternal Race - Japanese	No grouping for this variable
FRACE_NHW	Paternal Race - Native Hawaiian	No grouping for this variable
FRACE_OTH	Paternal Race - Other	No grouping for this variable
PAT_RACE	Paternal Race	
MAT_TRAN	Mother Transferred prior to Delivery?	
MM_LMP	Date Last Normal Menses - Month	
YY4_LMP	Date Last Normal Menses - Year	
MM_PCV	Date of 1st Prenatal Care Visit - Month	
YY4_PCV	Date of 1st Prenatal Care Visit - Year	
PNC_MTH	Month of 1st Prenatal Care Visit	
PNC_VST	Prenatal Visits (Total)	Grouped: < 8, 9-11; 12+
MOMLBS	Maternal Weight Gain	
MAT_WIC	Mother getting WIC Food during Pregnancy?	
MOMSMOKE	Did Mom Smoke?	
CIG_PRIOR	Cigarettes Smoked Prior to Pregnancy	
CIG_1TRI	Cigarettes Smoked In 1st 3 months	
CIG_2TRI	Cigarettes Smoked In 2nd 3 months	
CIG_3TRI	Cigarettes Smoked In last 3 months	
MOMCIG	No. of Cigarettes Smoked during Pregnancy	
PAY	Principal Source of Payment for this Delivery	
PRE_LB	Previous Live Births	Grouped: 0,1,2, 3-5, 6+
OTH_TERM	Previous Other Pregnancy Outcomes	
MM_DIAB	Gestational Diabetes	
MM_HBP	Hypertension	
P_PRTERM	Previous Preterm Births	
INFER_TR	Infertility Treatment	
MM_NOMD	No Medical Risk Factors	
MM_PROM	Premature Rupture of Membrane	

MM_FEVER	Chorioamnionitis	
DEL_VAG	Vaginal Delivery?	
DEL_FORC	Forceps Delivery?	
DEL_VACM	Vacuum Delivery?	
DEL_VCS	Vaginal Delivery after C-Section	
DEL_ICS	First C-Section?	
DEL_RCS	Repeated C-Section?	
GRAM	Birth Weight - Grams	Grouped: 250 gram increments
GEST_WK	Obstetric Estimation of Gestation	Grouped: <28 weeks, 28-33, 34-36, 37-42, >42 weeks
PLURAL	Plurality	truncate @ 3+
B_ORDER	Set Order	adjust to plurality
DEFECT	Congenital Anomalies	
TRANS	Infant transferred within 24 hrs of Delivery?	
ALIVE	Infant living at time of report?	
BRSTFED	Infant being Breastfed?	



## Section B. List of Core Questionnaire Variables and Operational Variables for Release to Researchers by CDC\*

\*Standard and state-specific questionnaire variables are available to researchers upon request

<i>Variable</i>	<i>SAS Label</i>
TYPE	Type of Survey Response (Mail/Phone)
VERS	Phase 5: Survey 1: QDE 1 (511, 512)
ID	PRAMS ID Number
<b>Core Questionnaire Variables</b>	
INSURE	Bef preg -- insurance
MEDICAD3	Bef preg -- Medicaid
VITAMIN	Multivitamin -- # of times /wk
MDOB_YR4	c) Moms birth -- year
MOMLBKGU	a) Moms weight -- lbs or kilos
MOM_LBKG	b) Moms weight -- bef preg
MOM_HTU	a) Moms height -- feet-inch/cm
MOM_FEET	b) Moms height -- feet
MOM_INCH	c) Moms height -- inches
MOM_CM	d) Moms height -- centimeters
PREV_LB	Previous -- live birth
PREV_LBW	Previous -- low birth weight
PREV_PRE	Previous -- premature
FEEL_PG	Preg -- intention
PREG_TRY	Preg -- trying
BC_WHEN4	BC -- use when got preg
NBC_MIND	a) No BC -- didn't mind preg
NBC_TIME	b) No BC -- couldn't at time
NBC_SIDE	c) No BC -- side effects
NBC_GET	d) No BC -- couldn't get
NBC_STER	e) No BC -- sterile
NBC_HUSB	f) No BC -- husb/part didn't want
NBC_OTH	g) No BC -- other
NBC_WHY	h) No BC -- other specified
SURE_PGU	a) Sure preg -- wks/mnths
SURE_PG	b) Sure preg -- time
PNC_1STU	a) 1st PNC visit -- wks/mnths
PNC_1ST	b) 1st PNC visit -- number
ERLY_PNC	PNC early -- as wanted
EP5APPT	a) PNC later -- no appt
EP5MONY	b) PNC later -- no money
EP5TRAN	c) PNC later -- no transportation
EP5LEAVE	d) PNC later -- no leave time
EP5START	e) PNC later -- no early ins care
EP5MEDI	f) PNC later -- no Medicaid card
EP5CHLD	g) PNC later -- no child care
EP5BUSY	h) PNC later -- too busy
EP5SECRT	i) PNC later -- keep preg secret

<i><b>Variable</b></i>	<i><b>SAS Label</b></i>
EP5OTH	j) PNC later -- other
EP5REAS	k) PNC later -- other specified
PP_MEDIC	a) PNC paid by -- Medicaid
PP_INCM	b) PNC paid by -- income
PP_IHMO	c) PNC paid by -- insurance/HMO
PP_state-spec1	d) PNC paid by --
PP_state-spec2	e) PNC paid by --
PP_OTH	f) PNC paid by -- other
PP_TYPE	g) PNC paid by -- Other specified
TLK_SMK	a) HCW talk -- smoking
TLK_BF	b) HCW talk -- breastfeeding
TLK_DRK	c) HCW talk -- drinking alcohol
TLK_BELT	d) HCW talk -- seatbelt use
TLK_BC	e) HCW talk -- postpartum BC
TLK_MEDS	f) HCW talk -- safe meds
TLK_DRUG	g) HCW talk -- illegal drugs
TLK_BDEF	h) HCW talk -- birth defects tests
TLK_LABR	i) HCW talk -- early labor
TLK_HIVT	j) HCW talk -- testing for HIV
TLK_ABUS	k) HCW talk -- physical abuse
HIVTEST	HIV test -- have dur preg
WIC_PREG	WIC -- dur preg
MORB_DIB	a) Morbidity -- diabetes bef preg
MORB_DID	b) Morbidity -- diabetes dur preg
MORB_BLD	c) Morbidity -- vag bleeding
MORB_KID	d) Morbidity -- kidney/bladder infect
MORB_NAU	e) Morbidity -- nausea
MORB_CRV	f) Morbidity -- cervix closed
MORB5BP	g) Morbidity -- HBP
MORB_PLA	h) Morbidity -- placenta
MORB_LAB	i) Morbidity -- preterm labor
MORB_PRM	j) Morbidity -- PROM
MORB_TRN	k) Morbidity -- Blood tranfusion
MORB_CAR	l) Morbidity -- car crash injury
MORB5LT1	a) Morbidity -- hosp <1 day
MORB51_7	b) Morbidity -- hosp 1-7 days
MORB5GT7	c) Morbidity -- Hosp >7 days
MORB5BED	d) Morbidity -- bedrest
SMK_2YRS	SMK -- >=100 cigs last 2 yrs
SMK5_3B	SMK -- 3 mnths bef, # cigs/day
SMK5_3L	SMK -- last 3 mnths, # cigs/day
SMK5_3N	SMK -- now, # cigs/day
DRK_2YRS	DRK -- last 2 years
DRK5_3B	DRK -- 3 mnths bef, drinks/wk
DRK5_3BB	DRK -- 3 mnths bef, five+ drinks/sit
DRK5_3L	DRK -- last 3 mnths, drinks/wk
DRK5_3LB	DRK -- last 3 mnths, five+ drinks/sit

<i>Variable</i>	<i>SAS Label</i>
STRS_FM3	a) Stress -- family member ill
STRS_DV3	b) Stress -- divorce
STRS_MOV	c) Stress -- moved
STRS_HOM	d) Stress -- homeless
STRS_JOB	e) Stress -- husb/part lost job
STRS_WRK	f) Stress -- mom lost job
STRS_ARG	g) Stress -- argue lots
STRS_PG	h) Stress -- husb/part preg no
STRS_BIL	i) Stress -- couldn't pay bill
STRS_FT4	j) Stress -- physical fight
STRS_JL3	k) Stress -- husb/part in jail
STRS_DRG	l) Stress -- others drugs
STRS_DH3	m) Stress -- others died
PAB_XHUS	a) Abuse -- 12 mnths b4 preg, ex-h/p
PAB_HUS	b) Abuse -- 12 mnths b4 preg, husb/part
PAD_XHUS	a) Abuse -- dur preg, ex-husb/part
PAD_HUS	b) Abuse -- dur preg, husb/part
DUE_MTH	a) Due date -- month
DUE_YR4	c) Due date -- year
DEL_MTH	a) Admin for del -- month
DEL_YR4	c) Admin for del -- year
IDOB_MTH	a) Infant birth -- month
IDOB_YR4	c) Infant birth -- year
DIS_MTH	a) Mom discharge -- month
DIS_YR4	c) Mom discharge -- year
PD_MEDIC	a) Delivery paid -- Medicaid
PD_INCM	b) Delivery paid -- income
PD_IHMO	c) Delivery paid -- insurance/HMO
PD_state-spec1	d) Delivery paid --
PD_state-spec2	e) Delivery paid --
PD_OTH	f) Delivery paid -- other
PD_TYPE	g) Delivery paid -- other specified
INF_ICU	Infant ICU -- at birth
BBY_HOSP	Hosp baby stay -- length of time
INFLIVE5	Infant alive -- now
INFWMOM5	Infant living -- with mom
BF5EVER	Breastfeed -- ever
BF5STILL	Breastfeed -- still
BF5LNGTU	a) BF duration -- wks/mnths
BF5LNGTH	b) BF duration -- length of time
BF5FOODU	a) BF oth food -- wks/mnths
BF5FOOD	b) BF oth food -- baby's age
SMK_EXP	Smoke exposure -- baby hrs
SLEEPPOS	Sleeping position -- baby
DR_1WK	Doctor -- baby visit 1st week
WBC_ANY	Well Baby C -- any visits
BC_NOW4	Postpartum BC -- using now

<i><b>Variable</b></i>	<i><b>SAS Label</b></i>
BCB_NSEX	a) PP BC barrs -- abstinence
BCB_PREG	b) PP BC barrs -- want preg
BCB_WANT	c) PP BC barrs -- didn't want to use
BCB_HUSB	d) PP BC barrs -- husb/part didn't want
BCB_INFT	e) PP BC barrs -- thinks sterile
BCB_PAY	f) PP BC barrs -- can't pay
BCB_PNOW	g) PP BC barrs -- preg now
BCB_OTH	h) PP BC barrs -- other
BCB_WHAT	i) PP BC barrs -- other specified
INC_JOB	a) Src income -- wages
INC_FAM	b) Src income -- family/friend aid
INC_DIV	c) Src income -- business/fees
INC5AID	d) Src income -- aid WIC/TANF
INC5UNEM	e) Src income -- unemployment
INC ALIM	f) Src income -- child support/alimony
INC_SS	g) Src income -- social security
INC5OTH	h) Src income -- other
INC_SRC	i) Src income -- other specified
INCOME5	Income -- 12 mnths bef, total income
INC_NDEP	Income -- dependents (+self)
TOD_MTH	a) Today's date -- month
TOD_YR4	c) Today's date -- year
<b>Operations Variables</b>	
BABYDEAD	BABY DEAD?
BATCH	BATCH NUMBER
MODECONT	Mode of contact
Particip	Did mom participate
mode_prt	Mail vs phone
urb_rur	urban-rural
hispanic	Hispanic?
inqx	In combined questionnaire
state	State
cell	Analysis Stratum
stratumc	Sampling Stratum
sud_nest	SUDAAN NESTing variable
nest_yr	Birth year for SUDAAN nesting
samcnt	sample count - weighting variable
totcnt	total count
wtone	sample wt
wttwo	nonresponse wt
wththree	noncoverage wt
wtanal	analysis wt
<b>CDC Analysis Variables</b>	
BC_GEST	VAR BC: COMPUTED GEST AGE (DAYS)
BC_YRLLB	VAR BC: YEARS SINCE LAST LIVE BTH
BF5AGE	VAR: # WEEKS FIRST FOOD
BF5WEEKS	VAR: # WEEKS BREASTFED BABY

<i>Variable</i>	<i>SAS Label</i>
DRK53B_A	VAR: YES/NO DRINK 3 BEF PREG
DRK53L_A	VAR: YES/NO DRINK LAST 3 MTH PREG
DRK5C_PG	VAR: CHANGE DRINKING DURING PREG
DUE_IDOB	VAR: DAYS BETW DUE DATE & BIRTH
EP5NUMB	VAR: # BARRIERS TO EARLY PNC
HSP_PG5	VAR: HOSP DURING PREGNANCY
INC_NUMB	VAR: # SOURCES OF INCOME
INFQ_AGE	VAR: INF AGE (DAYS) QUEST COMPLETED
INF_LIVE	VAR: INFANT ALIVE -- NOW
INF_WMOM	VAR: INFANT LIVING -- WITH MOM
MOM_BMI	VAR: MOM BODY MASS INDEX
MOM_BMIG	VAR: MOM BMI GROUPED
MOM_HT_I	VAR: MOM TOTAL HEIGHT (INCHES)
MOM_NITE	VAR: MOM NIGHTS IN HOSPITAL
MOM_WT	VAR: MOM WT BEFORE PREGNANCY
NOHOSP_B	VAR: BABY STAY IN HOSP?
NOHOSP_M	VAR: MOTHER DELIVERED IN HOSP?
PABF5_NO	VAR: NO ABUSE BEFORE PREGNANCY?
PAPG5_NO	VAR: NO ABUSE DURING PREGNANCY?
PD_NUMB	VAR: # SOURCES PAYMENT FOR DELIVERY
PNCNO	VAR: NO PNC VISITS
PNC_1TRM	VAR: START PNC 1ST TRIMESTER?
PNC_WKS	VAR: WEEKS 1ST PNC VISIT
PP_NUMB	VAR: # SOURCES PAYMENT FOR PNC
PREGHX	VAR: HX PREV LIVE BIRTHS (lbw, preterm etc)
QX_PHASE	QUESTIONNAIRE PHASE NUMBER
SMK53B_A	VAR: YES/NO SMOKE 3 BEF PREG
SMK53L_A	VAR: YES/NO SMOKE LAST 3 MTH PREG
SMK5C_NW	VAR: CHANGE SMOKING LAST 3 & NOW
SMK5C_PG	VAR: CHANGE SMOKING DURING PREG
SMK5C_PP	VAR: CHANGE SMOKING 3 BEFORE & NOW
SMK5NW_A	VAR: YES/NO SMOKE NOW
STRS_TT3	VAR: TOTAL # STRESSES
STRS_T_G	VAR: TOTAL # STRESSES, GROUPED
SURE_WKS	VAR: WEEKS WHEN SURE PREG
YY4_DOB	VAR: 4-DIGIT YEAR OF INFANT BIRTH (BC)
YY4_MDOB	VAR: 4-DIGIT YEAR OF MOTHER'S BIRTH (BC)

## **Section C. Letter of Agreement between CDC PRAMS and NAPHSIS, February 2010**

Dear PRAMS States and Vital Registries,

The CDC PRAMS Program and NAPHSIS have come to an agreement regarding sharing of the birth certificate data linked to the PRAMS survey for analysis. To summarize, our agreement:

1) Enables the creation of a basic PRAMS Research File for analysis (using grouped birth certificate variables), that does not require review by state registries of vital statistics; 2) Establishes a new, more specific data use agreement for the external researchers to sign in advance of receiving the basic PRAMS Research File; 3) Requires explicit, jurisdictional vital registry involvement/approval of any research requests for birth certificate data not specified in the attached documents; and 4) Requires a new data sharing agreement between CDC and states and vital registries.

Outlined below are the details regarding the PRAMS Research File, the review process and data use agreement with external researchers, procedures for requesting variables that are not part of the PRAMS Research File, and the data sharing agreements between CDC and states.

### **1) PRAMS Research File** (attached Appendix A- Birth Certificate Variables for Research File.xls)

The PRAMS Research File will include the following:

1. The STATE ID variable
2. Other agreed-upon birth certificate variables as indicated in the attached Appendix A, birth certificate variable list; variables to be excluded include the following:
  - a. Maternal Date of Birth – Year
  - b. Highest degree received (maternal and paternal)
  - c. Maternal height (BMI used instead)
  - d. Month of last live birth
  - e. Year of last live birth
3. Continuous birth certificate variables that will be collapsed as indicated in the attached Appendix A; of particular note are the following:
  - a. Maternal age
  - b. Smaller race groups (maternal and paternal)
  - c. Prenatal visits
  - d. Previous live births

- e. Birth weight
  - f. Gestational age
4. Truncated outliers for birth certificate variables (according to the data dictionary for the public use NCHS natality file)
  5. Core PRAMS questionnaire variables as indicated in the attached Appendix B (Questionnaire variables for research file.doc). These are released along with the previously specified birth certificate variables. Appendix B contains Phase 5 questionnaire variables names; however comparable variables from other questionnaire phases will be released if different questionnaire phases are requested. Standard and state-developed questionnaire variables will also be released, but only if requested by the researcher.

## **2) Review Process and Data Use Agreement with External Researchers**

### **A) Review Process**

CDC will revise the data request process. Researchers will submit an application form and proposal in abstract format with a specific list of states and years of data. Any standard or state-specific PRAMS variables will also need to be listed and submitted.

CDC PRAMS will review research proposals to ensure the suitability of PRAMS data to answer the research question. CDC PRAMS will send the proposals to states as a courtesy, but will not track approvals. State program staff (PRAMS staff or epidemiologists) may provide voluntary comments directly to researchers within a 2 week period. If a state chooses not to participate in a study, they should notify CDC within the 2 week period so their data can be excluded from the dataset. State program staff are welcome to share these proposals with state registries but active proposal review is not required by vital registrar for the release of the limited set of birth certificate variables (as described in point 1 above). Following the 2 week courtesy review period, CDC will prepare the requested dataset for the researcher.

### **B) Data Use Agreement with External Researchers** (attached PRAMS External researcher data sharing agreement.doc)

Before releasing the dataset, CDC will collect an External Researcher Data Use Agreement that each researcher must sign to assure compliance with the data sharing requirements.

One item in the External Researcher Data Use Agreement is the requirement to send publications and presentations to CDC for distribution to states prior to submission/presentation. CDC will emphasize this requirement to researchers (but is not in a position to enforce it). Once a publication or presentation is submitted to CDC by the researcher, CDC will distribute it to states to allow the opportunity to communicate concerns directly to the researchers within a 2 week time period. No comments after the 2 weeks indicate that there are no concerns, and the researcher may proceed with submission. For this publication review process, each PRAMS grantee should work directly with their state vital registry to establish a mutually acceptable review process, and keep the vital registry staff abreast of publications using PRAMS and linked birth certificate data. We hope that states and vital registries will accept this opportunity and communicate any concerns directly to researchers within the 2 week review timeframe.

### 3) Requests for variables NOT included in the PRAMS Research File

Any researcher requesting birth certificate variables **not** included in the PRAMS Research File, as specified in Appendix A, will not submit a proposal to CDC, but will be required to submit a proposal directly to the state(s) of interest. For such proposals, the researcher will need to comply with individual state vital registrar approval processes. Any proposed linkage to other individual data sets also requires active approval by states and vital registries. Linkage to append area data such as state level Census poverty indicators does not require additional review if only the research file is being used.

CDC will create the aggregate dataset for such requests only upon the researcher's submission of written approval from each relevant state vital registrar to CDC.

### 4) Data Sharing Agreement with States (attached 2010-2011 PRAMS Data Sharing Agreement.doc)

In order to document your agreement to share PRAMS data in the manner described above, CDC would like to obtain signed data sharing agreements from each PRAMS site and corresponding vital registry. This agreement would allow CDC to release the above described PRAMS Research File for the remainder of the current grant cycle.

Please obtain appropriate signatures on the attached Data Sharing Agreement with States document and mail the hard copy or email a scanned copy to Gary Stuart by **March 5, 2010**. Gary's contact information is as follows:

Gary Stuart  
Public Health Advisor  
PRAMS Team  
4770 Buford Hwy. NE, MS K-22  
Atlanta, GA 30341  
Email: [gstuart@cdc.gov](mailto:gstuart@cdc.gov)  
Phone: 770-488-5678

Please let me know if you have any questions.

Sincerely,

*Leslie L. Harrison*

Leslie L. Harrison, M.P.H.  
PRAMS Team Leader/Epidemiologist  
Division of Reproductive Health  
National Centers for Chronic Disease  
Prevention and Health Promotion