

Contents

1	Introduction	1-1
1.1	Purpose of the Pregnancy Risk Assessment Monitoring System (PRAMS)	1-1
1.2	History of PRAMS.....	1-2
1.3	Purpose and Use of the PRAMS Surveillance Protocol.....	1-7
2	Goals and Objectives.....	2-1
3	Personnel, Training, and Steering Committee	3-1
3.1	Project Director.....	3-1
3.2	Project Coordinator.....	3-2
3.3	Data Manager.....	3-4
3.4	Telephone Interviewers	3-6
3.5	Other Operational Staff.....	3-7
3.6	Spanish-Speaking Staff	3-7
3.7	Vital Records Contact Person	3-7
3.8	Data Analysts	3-9
3.9	Staff Training	3-10
3.10	Steering Committee.....	3-11
4	Sampling.....	4-1
4.1	Definition	4-1

4.2	Adjustments to the Sampling Frame.....	4-1
4.3	Sampling Plan	4-10
4.4	Selection of Sample.....	4-15
4.5	Frequency and Timing of Sampling	4-23
5	Data Collection	5-1
5.1	Data Sources.....	5-1
5.2	Methodology	5-1
5.3	Mixed-Mode Surveillance	5-3
5.4	Data Collection Instruments	5-7
5.5	General Data Collection Procedures	5-17
5.6	Mail Data Collection Procedures	5-24
5.7	Telephone Data Collection Procedures	5-32
5.8	Web Data Collection Procedures.....	5-36
5.9	Quality Assurance: Telephone Interviews	5-37
5.10	Methodologic Experiments	5-37
5.11	Alternative Methodologies.....	5-37
5.12	Recording and Reporting Data Collection Methodology	5-39
6	Data Management	6-1
6.1	Software Requirements for Daily Operations	6-1
6.2	Computer Platform Requirements	6-3
6.3	Virus Protection	6-4

6.4	Data Security and Personal Identifiers	6-4
6.5	Making Batch Data Available to CDC	6-6
6.6	Quality Control.....	6-8
6.7	Batch Reports.....	6-10
6.8	Creating the PRAMS Analysis File	6-11
7	Analysis, Use, and Limitations of PRAMS Data.....	7-1
7.1	Analyses by the State and CDC	7-1
7.2	Preparing for Analysis	7-2
7.3	Features of Analysis	7-3
7.4	Analytic Considerations	7-4
7.5	The State Analysis Plan	7-9
7.6	Conducting Analyses.....	7-12
7.7	Using and Disseminating Data from PRAMS	7-13
8	Authorship.....	8-1
8.1	General Authorship Principles	8-1
8.2	Review of Abstracts and Manuscripts.....	8-3
9	Timetable	9-1
9.1	Start-Up	9-1
9.2	Ongoing Activities.....	9-4

10	Human Subjects	10-1
10.1	Institutional Review Board (IRB) Protocol Submission and On-going Adherence	10-1
10.2	Informed Consent	10-1
10.3	Special Considerations.....	10-4
10.4	Protecting the Privacy of PRAMS Data	10-6
11	Evaluation.....	11-1
11.1	Sampling Evaluation.....	11-1
11.2	Operational Evaluation (OPAL)	11-3
11.3	Data Quality Evaluation	11-5
11.4	Evaluation of the Objectives of PRAMS	11-6
12	Glossary.....	12-1
 Appendixes		
A	PIDS Overview.....	A-1
B	Computation and Usage of Analysis Weights	B-1
C	Testing Results for State-Developed Questions.....	C-1
D	Rationale for Phase 6 Core Questions	D-1
E	Rationale for State-Added Questions: Standard and State-Developed.....	E-1
F	Standardized Letters for PRAMS Mailings	F-1

G	Standardized Telephone Introduction for PRAMS.....	G-1
H	PRAMS Mail and Telephone Questionnaires	H-1
I	Informed Consent Documents	I-1
J	Question-and-Answer Brochure	J-1
K	Calendar Enclosure	K-1
L	Resource List	L-1
M	Telephone Interviewer Monitoring Procedures.....	M-1
N	Performing Operational Experiments	N-1
O	State Configuration Reports.....	O-1
P	Guidelines for the Monthly Creation of the BCENTRY.DAT File	P-1
Q	Uniform File Layouts.....	Q-1
R	Guidelines for Collaborative Studies Using PRAMS Data: Examples of Data Sharing Agreements	R-1
S	State Analysis Plan	S-1
T	Guidelines for Preparing Manuscripts and Abstracts	T-1
U	Waiver for Prisoner Subjects.....	U-1
V	PIDS Data Security Plan	V-1
W	PIDS Data Sharing Agreement	W-1
X	Contracting Guidelines.....	X-1
Y	DELETED FOR 2014	

Z	Telephone Interviewing Procedures with Human Subjects Implications	Z-1
AA	Alternative Methods & Questionnaire Supplements Plans	AA-1
BB	Web Survey Screens and Emails	BB-1