9 Timetable

9.1 Start-Up

The major tasks to be accomplished during the start-up phase include the following:

- Hire and train state staff.
- Develop state protocol and submit to CDC program manager for review.
- Select state-specific questions and pretest any state-developed questions.
- Select birth certificate variables for data set.
- Develop sampling programs and procedures.
- Write and debug sampling programs.
- Organize and convene Steering Committee.
- Undergo local IRB review under Code of Federal Regulations, Title 45, Part 46 (45 CFR 46).
- Purchase equipment as necessary.

Work on most of these tasks needs to begin immediately after funding is received and the model protocol is received. With the availability of the model protocol, it is anticipated that the time frame from initial funding to data collection will take approximately 10-14 months. <STATE> needs to identify and mobilize project staff to work on project development tasks as soon as the model protocol is received. These tasks should be initiated according to the schedule below regardless of whether all project staff have been hired yet. If the PRAMS Coordinator position has not been filled, existing state staff members need to take responsibility for these tasks. The initial CDC site visit or orientation meeting will be scheduled as soon as possible after the model protocol is received and will provide the opportunity to clarify and discuss specifics of the project. After this visit, project development activities should be in full swing. Many of these development activities will be concurrent. Some activities will require considerable technical assistance from CDC. If any portions of the operations will be contracted out, steps to initiate these activities should be taken early enough to ensure that they are operational when needed. An additional site visit to review data submission procedures may be scheduled to coincide with the expiration of the first batch.

Protocol Development Task

The <STATE> protocol should include a start-up timeline with tasks and expected month(s) of completion. The dates in the following example apply to a state whose initial site visit by CDC occurs in Month 2. After meeting with the staff who will be participating in the development activities, prepare a start-up timeline for your state by modifying the example below as necessary.

Timeline of Start-Up Activities

Month 1 (Month funding is awarded.)
Read Model Protocol from CDC.
Initiate the hiring process for any staff that may need to be hired.
Make contact with Vital Records and identify a contact person who will work with PRAMS staff on sampling activities.
Initiate any contracts.
Begin process to purchase computer equipment and supplies.
Investigate state local IRB review process.

Month 2
Participate in initial CDC site visit or orientation meeting.
Begin completing Protocol Development Tasks.
Organize Steering Committee.
Begin investigating priority areas for the state analysis plan and for the state-specific portion of your questionnaire.
Identify stratification variable(s) of interest.

Month 3
As State Protocol chapters/appendixes are completed, submit to CDC for review.
Develop sampling scheme and sample size estimates.

Month 4
As State Protocol chapters/appendixes are completed, submit to CDC for review.
Project Coordinator should be hired.
Convene the first Steering Committee meeting to provide input on analytic priorities and state-specific questions.
Select topics for the state analysis plan and for the state-specific portion of your questionnaire.
Begin developing state-developed questions as necessary.
Submit sampling scheme and sample size estimates to CDC for review.

Month 5
As State Protocol chapters/appendixes are completed, submit to CDC for review.
Submit state-specific questions to CDC for review.
Identify state-specific birth certificate variables to be added to the data set.
Begin writing the sampling programs.
Schedule dates to go before the local IRB.

Month 6
As State Protocol chapters/appendixes are completed, submit to CDC for review.
Revise state-specific questions and return to CDC.

Month 7
As State Protocol chapters/appendixes are completed, submit to CDC for review.
Pretest and finalize any state-developed questions. Return final list of state-specific questions to CDC.
Submit sampling programs to CDC for review.
Schedule date for local IRB review.

Month 8
As State Protocol chapters/appendixes are completed, submit to CDC for review.
Submit final questionnaire to CDC.
Make revisions to sampling programs and submit to CDC.
Submit a test sample to CDC for review.

Month 9
Submit any remaining chapters/appendixes of State Protocol to CDC for review.
Submit completed questionnaire and draft of State Protocol to local IRB.

Month 10
Make final revisions to State Protocol and submit to CDC for review.
Submit final sampling programs to CDC for review.
Schedule dates for installation/training site visit with CDC.
CDC sends camera-ready copy of questionnaire to state.

Month 11
Secure IRB approval.
Four weeks prior to installation/training site visit, pre-installation conference call takes place between CDC and state to ensure all components are ready for data collection.
Print questionnaires.
Project Data Manager should be hired.
All project computer equipment should be acquired and operational.

Month 12
State draws first sample before CDC arrives for site visit.

CDC installs software in state and trains state staff in its use.
Begin data collection.

Month 13
CDC sends telephone version of questionnaire to the states.
Project Coordinator conducts telephone interviewer training using training materials provided by CDC.

9.2 Ongoing Activities

A surveillance system has many ongoing activities that need to be documented. It is particularly important to document milestones occurring to the project and significant changes to the surveillance methodology. Knowledge of methodologic changes can be useful during analysis to assist in interpreting results. It can also be useful on examining response patterns and implementing operational changes.

Protocol Development Task

Use this section of the protocol to record important events affecting the project over time. This timeline should reflect the ongoing activities in the state and should include dates for project milestones and any significant changes to the surveillance methodology. Documentation of ongoing activities will also provide information to include in the annual progress report required as part of the continuation application for PRAMS funding. Some examples include:

Start of data collection

Receipt of analysis data sets

Publications or presentations of PRAMS analysis

Annual renewal of IRB approval

Changes in methodology (stratification, incentives, sampling, alterations in data collection schedule, etc.)

Changes in staffing

Breaches in protocol or adverse events

Operational experiments Changes in state-specific variables Questionnaire revisions (change in priority topics, removal/addition of state-specific/standard questions, length of survey, major issues, implementation date, etc.) Changes in mailing packet materials (i.e. questionnaire cover, letters, resource list, etc.)