Protocol Development Process
NPS Vital Signs Monitoring Program

Key points:
- All monitoring protocols for which funding from the I&M program or the USGS Status and Trends Program is used for protocol development or protocol implementation (including time spent by people who have any portion of their salary funded by one of these programs) <u>must</u> (1) follow the Oakley et al. 2003 protocol standards, (2) be peer-reviewed, and (3) be approved by the Regional I&M Coordinator before they are finalized for long-term monitoring.
- **Protocol development is a difficult, expensive, time-consuming process that includes a research component**. Anyone who goes out into the field to collect some data and try out various methods, without first doing a lot of background work to build on existing information and data and other protocols, is wasting the taxpayer's money. No field work should be done until a study plan for protocol development with clearly defined objectives and a scope of work has been developed and received at least informal peer review.
- Field data collection, including collection of pilot data to determine variability of the measures, time/effort required for each sample, or to determine sample sizes needed to detect a certain level of change, should be one of the <u>last</u> steps of the protocol development process.

The vital signs monitoring program recognizes two classes of protocols, for which there are different rules for protocol development: (A) Existing, well-established protocols developed by another agency or program that have already been peer-reviewed and field-tested; and (B) all others. For the situation where I&M program funding is being used to continue or augment monitoring that was started years ago by a park, and many years of successful data collection and some documentation of the protocol and database already exist, it may be possible to start with Step B3, but the subsequent steps under B below must still be followed.

A. Existing Protocols developed by another agency or program that have already been peer-reviewed and field-tested: Examples would include protocols for the USDA Forest Service's FIA (Forest Inventory and Analysis) program, Breeding Bird Survey, MAPS (Monitoring Avian Productivity and Survival), Maryland Biological Stream Survey protocols, EPA EMAP or Canadian EMAN protocols, or air quality protocols for the IMPROVE or CASTNet programs.

<u>Note</u>: There is no need to completely rewrite existing, peer-reviewed and tested protocols to fit the Oakley et al. standards. We encourage people to build on existing work by adopting or modifying existing protocols. However, you do need to capture and archive a copy of the existing protocol and fill in the missing gaps to make it specific to the network parks and make sure that someone in the future understands why the monitoring was done, how it was done, how data were entered into NPS computers and made available for integration, how data were reported, etc. The existing, standard protocol can be cited as an appendix or SOP. Revision of the existing protocol might only require writing a 5 – 10 page protocol narrative and adding a

few SOPs on data management, analysis, and reporting. A second peer review is probably unnecessary if the protocol has already been reviewed, tested, and widely accepted (see A4).

A1. Download or create a digital copy of the protocol and all relevant SOPs; give it a version number; archive the protocol on a NPS computer so that people 10 or 20 years from now will understand how data were collected and managed.

A2. To facilitate collaboration among networks and for reporting by WASO to DOI and OMB and Congress, write a brief Protocol Development Summary for the protocol, including which parks it will be implemented in, and send copies to the Regional I&M Coordinator and National Monitoring Program Leader.

A3. Write a brief protocol narrative (with hyperlinks or page references that show where the details can be found in the standard protocol) and any SOPs needed so that someone in the future understands why the monitoring was done, how it was done, how data were entered into NPS computers and made available for integration, how data were analyzed and reported, and how revisions to the standard protocol will be incorporated.

A4. Send a copy of the protocol to the Regional I&M Coordinator for approval. The Regional I&M coordinator will decide if any additional peer review is needed for any sections or SOPs. An example of where additional peer review might be needed is where a network develops a spatial and temporal sampling design to implement the standard protocol in their parks, and formal review by a statistician is needed.

A5. Send a copy of the protocol to the National Monitoring Program Leader so that it can be posted to the NPS Protocol Database.

B. All Other Protocols for which I&M Program Funding is Used

B1. Do your homework. Thoroughly scope out the issues, monitoring questions, and objectives that will be addressed by the monitoring protocol. Answer the question, "who will use the monitoring results and how will they use the data?" Build on existing work and data: review relevant monitoring done by others, other relevant protocols or portions of protocols, and find and evaluate field data collected by others for similar situations.

B2. Write a Study Plan or Scope of Work for the proposed protocol development, and have it peer reviewed (at least informally). Remember, protocol development is an expensive, time-consuming process that involves a research component.

B3. Write a Protocol Development Summary (PDS) and send copies to the Regional I&M Coordinator and National Monitoring Program Leader to facilitate collaboration among networks and for reporting to DOI and OMB and Congress. The PDS is an executive summary of a detailed study plan that includes a brief justification statement, monitoring questions and a set of specific, measurable objectives, the basic approach/methodology to be followed (e.g., how you are building on previous work or existing protocols), who is going to develop the protocol, what it will cost, and how long it will take. It is not good enough to just have monitoring questions; the PDS should have a set of objectives that meet the test of being realistic, specific, and measurable. The PDS should list the parks that the protocol is expected to be implemented in within the next 3-5 years.

B4. Write a first draft of the protocol narrative and SOPs following the Oakley et al. 2003 standards. Find and evaluate existing field data and conduct simulations or other

analyses to determine what level of sampling is needed to detect different levels of change.

B5. Develop and document a relational database to manage and do summary analyses of the monitoring data.

B6. Send a copy of the draft protocol (with cautionary notes such as "DRAFT", "Still in Development", "Not Formally Peer-Reviewed" written on it) and draft database to the National Monitoring Program Leader so that it can be posted to the Protocol Database and shared with others.

B7. Implement the protocol, which means you start collecting field data for your parks following the draft protocol. If little or no relevant data or protocols existed for you to build upon (which is very rare), conduct one season of field sampling to test and refine your methods and study design. If there was existing work and data that you could build upon, go directly to Step B8 and have the protocol peer reviewed. Further testing and refinement of the protocol can occur after the formal peer review and approval steps.

B8. Have the protocol peer-reviewed. Your Regional I&M Coordinator has been delegated the authority to oversee the protocol peer review and approval process. Revise the protocol based on the peer reviewers' comments, and prepare a memo to the Regional I&M Coordinator and network files that explains how the peer review comments were addressed. (It is a good idea to have a 3-ring binder for each protocol, that includes original drafts, comments from peer reviewers, the memo showing how review comments were addressed, the revised protocol, and subsequent versions).

B9. Have the protocol approved by the Regional I&M Coordinator. Send a copy of the revised, approved protocol to the National Monitoring Program Leader to update the Protocol Database and for reporting accountability and performance to DOI, OMB and Congress.

B10. For several years, continue to test and refine the protocol and database. Revise the data management, analysis, and reporting procedures as needed. Follow your network's procedures for version control and archiving of the protocol narrative and SOPs.

B11. Periodically (e.g., every 5 years or as deemed appropriate), conduct a formal review of the protocol and resulting data to ensure that it is meeting the objectives and addressing park needs.