



Guidance for Developing, Reviewing, and Publishing Protocol Implementation Plans based on Published Source Protocols

Overview

To expedite protocol development, networks now have the option of formally adopting and implementing peer-reviewed protocols approved by other networks within NPS, or in use by other agencies. Networks may now submit a Protocol Implementation Plan (PIP) to their regional program manager for approval in lieu of a full traditional Protocol. This option is not intended to reduce the scientific rigor of the monitoring methods used by the Inventory and Monitoring Division (IMD)—rather to leverage the efforts of partners internal and external to IMD and to encourage consistency of methods and data across networks and between NPS and partner agencies.

What's in a Protocol Implementation Plan?

A PIP is a short (approximately 10-20 pages) document that describes how a published “source” protocol will be used to meet one or more monitoring objectives for an I&M Network. The purpose of the PIP and associated review process is to provide the information justifying—and make the determination—that planned deviations on the whole do not constitute a major departure from the source protocol and that the use of the protocol is appropriate for the stated monitoring objectives. A PIP is not intended to be an exhaustive scholarly document, but rather a high-level summary of how the source protocol will be implemented by the Network within the framework outlined in Oakley et al (2003).

An example Draft PIP is available to illustrate the type of information and level of detail expected are available on the IMD SharePoint site at: <http://goo.gl/mO7uwf>. Additional examples will be uploaded as they are completed.

1. Introduction

This section summarizes the scientific, scholarly, or procedural reason for conducting the monitoring, as described in the protocol development summary (if available from the network's approved Vital Signs Monitoring Plan) with any necessary updates. Additionally, this section should clearly identify and cite the source protocol(s) that will serve as the basis for monitoring and a summary of deviations from the source protocols, presented in either bullet, tabular, or narrative formats. Procedural-level changes are detailed in the summary of standard operating procedures.

2. Conceptual Framework for Monitoring

This section provides information about the management and ecological context in which monitoring will be conducted, and clearly indicates what will and what will not be monitored as a part of the protocol (and what

data will be made available through other monitoring efforts). Information is to be presented in a table (see Table 1 of [the provided PIP example](#)). This section is informed by—or summarizes information within—conceptual models developed in each network’s Vital Signs Monitoring Plan.

3. Measurable Objectives

There is wide variation in how monitoring objectives are written across networks and agencies, and in most cases monitoring objectives as presented in Vital Signs Monitoring Plans were not in “SMART” format (Specific, Measurable, Achievable, Realistic, and Timely). In addition to specifying what monitoring objectives will be addressed, this section explicitly states whether the monitoring objectives are a) adopted from source protocols verbatim, b) adopted but rewritten to be “SMART” as appropriate, or else c) the Plan must clearly indicate that the methods being adopted with deviations as presented are appropriate for achieving monitoring objectives as written.

4. What’s being Measured and How

This section provides an overview of field sampling and data collection methods based on SOPs in the source protocol(s). Any operational implementation notes, requirements, or opportunities can be mentioned here (availability of equipment, similar work being done by parks or others, permitting requirements, etc.). This section clearly cites all source methods being used, including a table that clearly specifies for each monitoring objective the field methods to be implemented and the resultant data that will be used for analysis.

5. Sampling Design & Monitoring Schedule

This section briefly summarizes the spatial and temporal sampling designs for each objective. Sampling design choices can be made based on existing methods as prescribed in source protocols, can be modified from source protocols to accommodate park-specific logistical constraints, or can be driven by power analyses of data that have already been collected. In cases where power analyses are included, they should be included as an appendix, or (preferably) reviewed/published independently of the PIP and cited.

6. Data Management, Analysis, & Reporting

The Data Management section must identify all data sets / types to be collected, and identify data processing and data quality assurance certification workflows required for the protocol. The anticipated timeline / frequency for data certification, analysis, and reporting must be specified.

To help identify procedures necessary, a suggested matrix of data processing and data quality levels is provided with the PIP template. All data that are collected start as raw and unprocessed; and are subsequently processed for use in analysis. All datasets, regardless of processing levels must be certified, documented, and published, either as datasets or program records¹.

¹ Guidance on records management for Networks is forthcoming. In the interim, we’re asking that networks identify what the protocol-related records are, and specify the procedures required to manage them appropriately. These procedures should align with each network’s data management plan, which should have a section on records management and archiving requirements.

In cases where it is appropriate to provide provisional data to parks for management or planning purposes, this should be noted, and any requirements for data quality control applicable to provisional data should be specified in supporting SOPs.

7. Budget

The PIP includes an annual budget with staffing, equipment, and travel costs, and clearly summarizes total start-up costs. If costs are shared, the budget must be split to clearly show total costs to the network. Budgets must reflect an accurate estimate of implementation in the absence of partnerships or integration with other network operations. Staffing must account for a portion of personnel costs associated with data management, analysis, and reporting, and equipment & supplies costs must account for recurring maintenance costs. However, budgets will *not* account for potential efficiencies gained through concurrent implementation with other protocols (i.e., do not halve travel costs if two protocols are implemented during field work).

In cases where costs vary by year due to sampling schedules, costs can be presented as a range, or costs can be presented by year along with an average implementation cost.

Any significant cost savings that can be achieved based on leveraging partnerships or coordination with other efforts should be noted in text.

8. Safety

A risk assessment must be conducted to identify significant safety concerns and to determine if the protocol can be implemented safely without negatively impacting the network's ability to meet monitoring objectives. This includes an analysis of job hazards encountered in all aspects of protocol implementation, and relevant safety SOPs should be included in Section 9 as described below.

9. Standard Operating Procedures and Deviations from Source Protocol(s)

All SOPs required to implement the protocol must be identified, including all those required for data collection, management, reporting, and safety. These can come from protocols *in addition to* the identified source protocol, but data collection and analysis SOPs should come primarily from source protocols. In many cases SOPs will need to be rewritten based on source SOPs to make them specific to the adopting network's geographic setting, equipment, or personnel. Section 9 must clearly indicate the source SOP, explanation of any differences, and provide a link to the SOP to be implemented in the adopting network. For SOPs published in the NPS Data Store, links must be provided for the record (not the file) to ensure readers are directed to the most-current version.

The table of SOPs must include:

- Procedures for all data collection methods and analyses presented in Section 4.
- Site selection (if not a census design) methods and data analysis methods (if known) as presented in Section 5.
- Data management SOPs to guide data processing, analysis, and data certification workflows for all datasets identified in Section 6.
- Safety SOPs to mitigate significant safety concerns identified in Section 8.

It is strongly recommended that data analysis SOPs be included that cover the “Routine statistical data used to compute standard indicators and trends that are gathered using methods based on well-established, peer-reviewed protocols and are analyzed and interpreted within the guidelines of the protocols.” This will allow networks to publish findings in the Natural Resource Data Series without peer review as allowed under Director’s Order #11b (NPS 2008).

Changes to procedures will be considered as a part of the review process. Individual SOPs cannot include new methods that have not been through an appropriate technical review process (you cannot introduce new non-peer-reviewed methods via a PIP), and the collection of the SOPs to be implemented as a part of the full protocol must not constitute a major deviation from the source protocol.

When and How to Develop a Protocol Implementation Plan

A PIP is only appropriate for use in adoption and implementation of a protocol that can meet one or more monitoring objectives that has been peer reviewed and approved for implementation by IMD, or alternatively published and implemented by an external agency. Although modifications to source protocols are allowed, they should ideally be minor—such as clarification of monitoring objectives, updating equipment, modifying reporting goals, or tailoring sampling designs to local study areas). It is not appropriate to add new monitoring objectives, or new methods above and beyond what exists in published literature. Suggestions for developing a PIP are to:

1. Identify a source protocol that will meet one or more monitoring objectives relevant to your program. When trying to identify a potential “source” protocol, preferred options are those in use by other federal or state agencies, or other networks within IMD where monitoring objectives and ecosystems to be monitored are similar. To see what other protocols are being implemented within IMD, please see the Protocol Tracker Database <http://irma.nps.gov/protocoltracking/>.
2. Although it is acceptable to adopt scientific procedures from multiple protocols, this should be limited, unless multiple source protocols are necessary to address individual monitoring objectives. In cases where monitoring objectives require methods from separate protocols, then develop PIPs for each protocol. For example: separate out species community, water quality, and physical habitat components of “integrated” protocols into three separate PIPs citing relevant source protocols. This will expedite the review process.
3. Procedures in source protocols may be updated based on peer-reviewed literature. This is particularly useful for older protocols where new equipment, software, or analysis techniques have been developed since the original protocol’s publication.
 - a. For data collection procedures, the PIP must clearly show that the updated methods meet requisite data quality standards as outlined in the source protocol.
 - b. For data processing and analysis procedures, the PIP must clearly show that the updated data processing and analytical methods are appropriate for the data being collected, and provide information sufficient to meet the monitoring objectives.

- c. Changes to the sampling design may be made based on peer-reviewed publications that evaluate existing pilot data and present recommended sampling designs based on those analyses. Where peer reviewed analyses of pilot data do not exist, networks may include their justification in an appendix to the PIP. Authors should be aware, however, that Regional Program Managers may require that such analyses be formally written, reviewed, published, and cited prior to approval of the PIP.
4. For protocols that can be “mostly” adopted or implemented using published and approved methods, but require some pilot work to fully implement as planned, the recommendation is to document what can be implemented based on existing methods only. Additional monitoring objectives and associated standard operating procedures can be addressed in separate full monitoring protocols, or in an updated PIP once a suitable source protocol be published and approved.

Peer Review and Publication Requirements

Protocol implementation plans will not be subject to full, independent peer review like traditional IMD protocols. Instead, Regional Program Managers will conduct or arrange limited independent reviews to evaluate a) utility of the proposed protocol to meet IMD monitoring objectives and b) the effects of proposed modifications that have been made to a protocol or procedure for use by IMD. Modifications may include slight changes in protocol objectives, alterations in plot design, changes in sample size, changes in equipment, network-specific data management and certification procedures, etc. In such cases, the purpose of limited independent reviews is to ensure that any modifications to source protocols do not significantly impact a) the quality of information being collected, b) the ability to analyze those data following planned methods, or c) the likelihood of meeting monitoring objectives.

Regional Program Managers must serve as peer review managers for PIPs, and reviews must include any revised SOPs as a part of the review. Findings of the peer review must explicitly document the determination whether the proposed adoption of a source protocol is appropriate as well as any necessary changes to ensure the PIP meets the criteria above. Plans that cannot meet the criteria must be developed into full protocols.

To ensure that the Peer Review Manager has all appropriate materials for making this determination, Network Program Managers should submit the following:

- Protocol Implementation Plan document
- Source protocol(s) used as the basis for the PIP
- All SOPs to be used in protocol implementation.
- Any additional supporting material as requested, such as names of individuals who have reviewed SOPs, or written communications or unpublished analyses cited to justify deviations from source protocols.

The reviews are to be conducted by experienced professionals (NPS or otherwise) having direct experience with the subject matter or protocol being implemented. It is recommended that if an approved protocol developed within IMD is used as the source, that the source program manager or protocol lead serve as a

courtesy reviewer. This will assist in a) determination that a PIP is an appropriate vehicle for documenting monitoring methods, b) ensuring appropriate attribution of the source protocol, c) provide an opportunity to provide updated SOPs for inclusion, and d) promote coordination among networks implementing similar methods. Note, however, that the intent of the review is *not* to determine if/how the source protocol's authors would implement the protocol in the adopter's network.

A standard peer review form for PIPs has been developed and is available on the IMD SharePoint site at: <http://goo.gl/mO7uwf>. It is recommended that the form and this guidance be provided to any external reviewers along with the materials to be reviewed.

Network Program Managers may serve as peer review managers for Standard Operating Procedures, but SOPs are subject to revisions as mandated by Regional Program Managers to obtain approval of PIPs.

Authorship and Attribution Notes²

In general, the authors of a PIP should include the network program manager, protocol lead, and data manager as the three people most accountable for the plan's implementation. The author of the source protocol should generally *not* be an author unless he/she specifically wrote the plan (or serves the network in one of the roles mentioned above). It is incumbent on the plan's authors to cite the source protocol and all relevant SOPs as published scientific literature, and to appropriately present the source protocol's purpose, limitations, and applicability for use outside its originally-intended scope.

Publication

All PIPs must be published in the Natural Resource Report Series and must be published to the Data Store as a "Protocol" document type. Plans must be updated at the same frequency as full protocols (approximately once every five years) pending a protocol review. New SOPs created specifically in support of the Plan must be published as individual documents or as a single collection of SOPs, but must be published independently of the PIPs. SOPs must also be published in the Data Store, but as a "Standard Operating Procedure" document type.

Updates or revisions to the PIP and associated SOPs must be uploaded to the Data Store using the "versioning" capabilities. New versions of the Plans must be approved by the Regional Program Manager prior to submission. New versions of SOPs may be approved by Network Program Managers, but do not trigger a re-review of associated PIPs if versioning is used.

References

National Park Service (NPS). 2008. [Proposed update to Director's Order #11B: Information Quality – Ensuring objectivity, utility, and integrity of information used and disseminated by the National Park Service](#).

National Park Service (NPS). 2015. Guidelines for determining authorship on scientific and scholarly products developed by the Inventory and Monitoring Program.

² This guidance is to be considered *in addition to* the general authorship guidelines for IMD (NPS 2015).

Oakley, K. L., L. Thomas, and S. G. Fancy. 2003. Guidelines for long-term monitoring protocols. Wildlife Society Bulletin 31:1000-1003.