

Guidance for Protocol Reviews: Targeted Science Reviews

Overview

This document is intended to provide guidance on how to conduct Targeted Science Reviews, as called for in Core Expectations for Vital Signs Monitoring:

- #2 “Use Peer-reviewed Study Designs to Guide Collection of Monitoring Data” and
- #3 “Ensure Scientific Excellence and Integrity.”

Described herein are the Purpose, Triggers, Process and Roles, Outcomes, and Required Questions that must be answered for a Targeted Science Review to be properly conducted.

Purpose

Opportunities or situations may arise that require modifying or adjusting portions of a protocol without requiring a Full Science Review. A Targeted Science Review is designed to only review a component of a protocol (e.g., narrative sections, SOPs, Quality Assurance Plans, or Supplementary Materials) and to propose substantive changes, if warranted. *(Note: In most instances, SOPs are revised as part of an operational review. Only when substantive changes are proposed to a portion of a protocol that directly affects field procedures would the SOP need review. This should be determined in consultation with the RPM.)*

Targeted Science Reviews will generally occur when there is a specific aspect of a protocol that is problematic, or when a network is considering a major or substantive change to one aspect of a protocol. Major or substantive changes are alterations that have the potential to affect the ability to compare data over the period of record, such as changes to sampling designs, parameters being measured, or data-quality standards.

A Targeted Science Review can also address other aspects of a protocol, such as relevance and sustainability. Whereas a Full Science Review evaluates all monitoring objectives and protocol components, a Targeted Science Review evaluates a subset, leaving other protocol components unreviewed. A Targeted Science Review is not a substitute for a Full Science Review.

Triggers

Potential triggers for a Targeted Science Review include:

- Findings of an Operational Review.
- Outcome of a Network Program Review.
- Concerns raised as a result of data QC and analyses.
- Network or park staff concerns about data credibility, relevance, or utility.
- Safety considerations.
- Availability of new or alternative approaches or tools.
- Sustainability concerns.

- Desire to collect additional co-variate data that may require substantial additional time and effort.
- Equipment or technology change/update.

Process

The Regional Program Manager (RPM) should be consulted to help determine whether proposed changes to a protocol merit a Targeted or a Full Protocol Review. It is the responsibility of the Network Program Manager (NPM) and RPM to develop the scope of the Targeted Science Review, including level of peer review and who reviewers should be. Questions that target the source of the problem will be determined by the NPM, RPM, and Protocol Lead.

Roles and Responsibilities

Protocol Lead/Other Network Staff

1. Identifies issue/conflict in the protocol that needs resolving and discusses options with Network Program Manager (NPM).
2. Provides support and coordination to the NPM in developing the scope of the review, review planning, and compiling review materials/products.
3. Implements changes to protocol based on review recommendations and approval by Regional Program Manager and Network Program Manager.

Network Program Manager/Protocol Lead

1. In conjunction with Protocol Lead and RPM, develops the review objectives, scope and design of the review, and review questions.
2. Selects appropriate reviewers.
3. Develops a plan for a review process relative to:
 - a. how questions will be answered, or
 - b. a clear justification for waiving them if they have been addressed by previous actions, or
 - c. are out of scope.
4. Formulates a review response summarizing actions to be taken based on the Reviewer comments and RPM Review Summary document.
5. Works with Protocol Lead to implement changes.

Regional Program Manager

1. Coordinates with the NPM to initiate the review.
2. In conjunction with the Protocol Lead and NPM, develops the review objectives, scope and design of the review, and review questions.
3. Produces and approves the review scope and review plan for ascertaining reviewer input.
4. Drafts a summary of reviewer comments, providing oversight and approval for protocol changes recommended by the reviewers.
5. Approves network response and course of action for any revisions to the protocol.

Reviewers

1. To address questions of scientific integrity and protocol efficiency questions: Up to three technical subject-matter experts.
2. To address data management issues: Up to three technical experts, including external data-management and protocol-lead experts.

Outcomes

- The primary outcome of a Targeted Science Review is an assessment of the specific issue that motivated the review and the recommended modifications to the protocol component.
- The network produces a review summary and response explaining how reviewers' recommendations will be addressed, and the situation resolved.
- The proposed actions are reviewed and approved by the RPM.
- All documents related to the review should be maintained by the network in accordance with records management practices.
- A DataStore assemblage of examples outcomes, products, and templates for Targeted Science Reviews will be populated as materials become available.