

# EPC Program Procedures Guide

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**Agency for Healthcare Research and Quality  
Center for Evidence and Practice Improvement  
Evidence-based Practice Center (EPC) Program**

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### Introduction

This Procedure Guide describes the process for developing evidence reviews for the Evidence-based Practice Center (EPC) Program in order to promote consistency and high quality for AHRQ reports and to foster a common understanding of the steps needed to complete an evidence review by an EPC. AHRQ will update this guide periodically to reflect process changes.

All who work with the EPC Program have a shared goal: that the program's products be useful, relevant, and understood by end-users. EPCs should consult their TOO about issues that may affect the consistency of EPC products and their quality.

The guide will refer to related documents that include greater detail or more specific guidance—such as templates, exemplars, or other resource documents—and will indicate the role of other groups in relation to the development of an evidence review. The descriptions of these other entities—such as the Task Order Officer (TOO), and Scientific Resource Center (SRC)—are not intended to be all encompassing. While detailed, this document should be considered guidance; it is not comprehensive.

We have organized this Procedure Guide into chapters to minimize redundancy, and make it easy to use and update. The steps for the “flagship” EPC product—a combined topic refinement with systematic review—have been described in full. Other products, such as a technical brief or stand-alone systematic review, follow these processes except where noted. Optional steps are designated by italics. Two partners, the CMS Technology Assessment (TA) and the NIH Pathways to Prevention (P2P) programs, have special requirements that require adaptation of particular steps; these appear in bold throughout.

“Templates” require a specific format and are used for all publicly facing documents, where uniformity is necessary. Content guidance provides additional details about a deliverable and may be used in conjunction with a template (such as with a draft report).

We thank many individuals who contributed to the development and revision of this Procedures Guide, including AHRQ TOOs, EPC project managers, and the SRC.

We welcome your questions about how develop EPC program evidence reports, and ways to improve their quality and efficiency. Please send your questions to Stephanie Chang ([stephanie.chang@ahrq.hhs.gov](mailto:stephanie.chang@ahrq.hhs.gov)), director of AHRQ's EPC Program.

### **Roles and Responsibilities**

Developing high quality EPC Reports requires coordination between AHRQ, Contractors, and External Partners. This section describes roles and responsibilities for these groups.

#### **AHRQ:**

Evidence-based Practice Center Program Division (EPC Program): Within AHRQ's Center for Evidence and Practice Improvement (CEPI), the EPC Program Division manages the EPC contracts and is responsible for the final products (systematic reviews, technical briefs, etc.).

- AHRQ-EPC Program Leadership: AHRQ's EPC Program Director (Division Director) or designee.
- AHRQ-EPC Program Coordinator: supports the EPC Program by managing tasks such as tracking projects, timelines and deliverables across the EPC Program; routing deliverables for posting; and assisting with other logistics.
- Task Order Officer (TOO): provides some scientific oversight, and ensures that the executed task order is consistent with EPC Methods and Procedures. The TOO also functions as the Contracting Officer Representative (COR): an individual appointed by the Contracting Officer to assist in the technical monitoring or administration of a contract.

Office of Communications (OC): This office is responsible for communicating to internal and external AHRQ customers. For the EPC Program, OC develops and manages dissemination plans for EPC products; edits Final Reports for posting on the Effective Health Care (EHC) website and National Library of Medicine (NLM) bookshelf; manages public affairs and media activities; and coordinates co-publication of the Final Report with journal manuscripts.

#### **AHRQ CONTRACTORS:**

Evidence-based Practice Center (EPC): Under the EPC Program, AHRQ awards multi-year contracts to organizations across US and Canada. Only EPCs can compete for Program task orders to develop specific evidence reports/products.

- EPC Director: Responsible for the EPC contract. The Director must review the Draft and Final Reports and attest to their integrity and quality before the EPC submits reports to the AHRQ TOO.
- EPC Principal Investigator (PI): Based on the topic, the EPC chooses a unique principal investigator (PI) to oversee the scientific content of each report. The PI is responsible for management of the team, oversight of project tasks, and communications with AHRQ.
- EPC Program/Project Manager: Manages the EPC side of report production, coordinates staff, manages logistics, and helps the EPC meet timelines.

## Roles and Responsibilities

- Associate Editor (AE): Experienced investigators from EPCs who review and provide feedback on Draft and Final Reports. AE reviews aim to improve consistency and quality across EPC Program products.

Scientific Resource Center (SRC): This organization manages centralized activities for the EPC Program. The SRC promotes the scientific credibility and independence of program products by managing peer review, providing technical support for topic nomination and selection processes, and convening methods work.

### EXTERNAL STAKEHOLDERS:

Partner: For most EPC products, AHRQ identifies a Partner prior to award. The Partner may be a professional society, healthcare organization, or Federal agency that intends to use the EPC product. This use may include a specific healthcare decision, meeting, or clinical practice guideline or recommendation. The Partner or the constituency it represents is the primary audience for the report. The Partner will typically help the EPC identify the key decisional issues in the topic area of the report.

- Sponsoring Partner: usually a Federal agency provides funding via an interagency agreement (IAA) for developing the EPC product. Sponsoring Partners have included agencies such as National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Centers for Medicaid and Medicare Services (CMS), Department of Transportation (DOT), and Office of the Assistant Secretary for Health (OASH).

The CMS Coverage and Analysis Group is the Sponsoring Partner for the ongoing Technology Assessment (TA) Program. Systematic reviews developed under this program inform CMS decisions via deliberations on the evidence at Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meetings.

The NIH Office of Disease Prevention is the Sponsoring Partner for the NIH Pathways to Prevention (P2P) Program. AHRQ provides the systematic reviews to inform NIH workshops that identify research gaps in a selected scientific area, identify methodological and scientific weaknesses in that scientific area, suggest research needs, and move the field forward through an evidence-based assessment of a complex public health issue.

- Non-sponsoring Partners: do not provide funding for the EPC product, but have plans to use or disseminate the final report, such as through guideline development. Topics from non-sponsoring partners generally come through the nomination portal on the EHC website.

Key Informant (KI) for systematic reviews: The primary role of the KI is to provide additional context around the decisional issues; and help the EPC refine and focus the Key Questions, PICOTS, and Analytic Framework during the topic refinement stage. For systematic reviews, Key Informants may help the EPC focus the review by identifying the primary outcomes of interest, the types of comparisons that they are most concerned about, or the patient populations around which there is the greatest uncertainty. The KI panel may include patients, caregivers, practicing clinicians, researchers, professional or consumer organizations, purchasers of health care, and others who make health care decisions relevant to the topic. KIs are stakeholders in the

## Roles and Responsibilities

decisional dilemmas at the heart of the report and may not be content, clinical, or methodological experts.

Key Informants for Technical Briefs: KIs for these products do not refine the guiding questions but rather inform them, given that the technologies in questions are generally fairly new and relatively little written data may be available about clinical outcomes. Therefore, KIs can contribute to an understanding of how the technology/intervention works, where it might fit into clinical care, and potential advantages or concerns. The ideal role for Key Informants is to reveal questions and concerns from a user/practitioner perspective that may not appear in the literature. KIs may include subject experts and end users of the technology/intervention, such as patients and caregivers, practicing clinicians, medical directors, Pharmacy and Therapeutics (P&T) or similar committees, relevant professional and consumer organizations, purchasers of healthcare, and others with experience in making healthcare decisions relevant to the topic.

Technical Expert Panel (TEP) for systematic reviews: The TEP informs the scientific approach for the systematic review, particularly the Protocol. The TEP usually includes one or more clinical providers, methods experts, experts from relevant federal government agencies, relevant professional society and health care purchaser representatives, and other content experts. The Technical Expert Panel size and composition should create a balance between content and methodology expertise and the user's perspective. These individuals should have no professional or financial conflict with the content of the report as defined by the EPC Policy on Financial and Nonfinancial Interests. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified. Individuals can serve as both a TEP member and a KI.

Peer Reviewers: Peer reviewers provide comments on a draft report. These individuals are similar to the TEP in background and expertise. Peer reviewers have no professional or financial conflict with the content of the report as defined by the EPC Policy on Financial and Nonfinancial Interests; and have not previously served as a KI or TEP for the draft report they review. Because of their unique clinical or content expertise, individuals with potential non-financial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential non-financial conflicts of interest identified.

## **Useful Web Sites, Email Addresses, and Guides**

### **Web Sites**

AHRQ	<a href="http://www.ahrq.gov">www.ahrq.gov</a>
Effective Healthcare Program	<a href="http://www.effectivehealthcare.ahrq.gov">www.effectivehealthcare.ahrq.gov</a>
PROSPERO	<a href="http://www.crd.york.ac.uk/NIHR_PROSPERO/">http://www.crd.york.ac.uk/NIHR_PROSPERO/</a>
Scholar One	<a href="http://mc.manuscriptcentral.com/ehc">http://mc.manuscriptcentral.com/ehc</a>
SRC Secure Site	<a href="http://www.epc-src.org/src/logon.cfm">http://www.epc-src.org/src/logon.cfm</a>
Systematic Review Data Repository (SRDR)	<a href="http://www.srdr.ahrq.gov">www.srdr.ahrq.gov</a>
Technology Assessment Program	<a href="https://www.ahrq.gov/research/findings/ta/index.html">https://www.ahrq.gov/research/findings/ta/index.html</a>

### **Email Addresses**

EPC Program coordinator	<a href="mailto:EPC@ahrq.gov">EPC@ahrq.gov</a>
Methods workgroups	<a href="mailto:methods@epc-src.org">methods@epc-src.org</a>
ScholarOne questions	<a href="mailto:review@epc-src.org">review@epc-src.org</a>
SRC Secure Site	<a href="mailto:admin@epc-src.org">admin@epc-src.org</a>
SEADs and Federal Register notices	<a href="mailto:EPC@ahrq.hhs.gov">EPC@ahrq.hhs.gov</a>
Topic Selection	<a href="mailto:topics@epc-src.org">topics@epc-src.org</a>
Web-based Disclosure Form and Acknowledgement and Confidentiality Form	<a href="mailto:admin@epc-src.org">admin@epc-src.org</a>
SRDR	<a href="mailto:SRDR@ahrq.gov">SRDR@ahrq.gov</a>

### **Guides and Training Modules**

EPC Methods Guide for Effectiveness and Comparative Effectiveness Reviews  
<https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview/>

EPC Methods Guide for Medical Test Reviews  
<https://effectivehealthcare.ahrq.gov/topics/methods-guidance-tests/overview-2012/>

AHRQ Training Modules for the Methods Guide for Medical Test Reviews  
<https://effectivehealthcare.ahrq.gov/topics/methods-guidance-tests/slides>

AHRQ Training Modules for the Systematic Reviews Methods Guide  
<https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/slides-2010>

## **Graphic Overview**

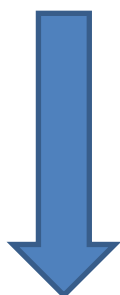
### *Overview: Topic Development, Topic Refinement and Systematic Review*

#### Topic Development



- Pre-Kickoff Activities
- Kickoff Call
- Content Expert Input
- Draft Topic Development Brief
- Presentation to Decision-making Group for Input
- Finalized Topic Development Brief
- Partner notification of topic's disposition
- Respond to feedback

#### Topic Refinement



- Pre-Kickoff Activities
- Kickoff Call
- Assemble Key Informant Panel
- Topic Refinement Document, Part 1
- KI Calls
- Topic Refinement Document, Parts 2 and 3
- Posting of Topic Refinement Part 3 (KQ Posting Document) for Public Comment
- KQ Comments Call
- Draft Protocol

#### Systematic Review

- Assemble Technical Expert Panel
- 1st TEP Call
- Final Protocol and Posting
- SEADs and optional Federal Register Notice
- Literature Review
- *Optional TEP Calls*
- Monthly Update Calls
- Proposed Peer Reviewer List
- Preliminary list of included studies and mock-up of summary tables
- Draft Report
- Peer Review
- Presentation of Draft Report findings
- Peer-reviewed Draft Report (if sequential peer review and public comment)
- Posting of Draft Report for Public Comment
- Literature update
- Final Report and Disposition of Comments
- Post-report Activities



*Overview: Standalone Systematic Review (without Topic Refinement)*

Systematic Review

- Pre-Kickoff Activities
- Kickoff Call
- Draft Protocol
- Assemble Technical Expert Panel
- 1st TEP Call
- Final Protocol and Posting
- SEADs and optional Federal Register Notice
- Literature Review
- *Optional TEP calls*
- Monthly Update Calls
- Proposed Peer Reviewer List
- Preliminary list of included studies and mock-up of summary tables
- Draft Report
- Peer Review
- Presentation of Draft Report findings
- Peer-reviewed Draft Report (if sequential peer review and public comment)
- Posting of Draft Report for Public Comment
- Literature update
- Final Report and Disposition of Comments
- Post-Report Activities

## Graphic Overview

### *Overview: Surveillance*

- Pre-kickoff call activities
- Kickoff Call
- Assemble Content Experts
- Literature Scan
- Findings Matrix
- Content Expert Input
- Surveillance Report
- Monthly Update Calls
- Post-report Activities

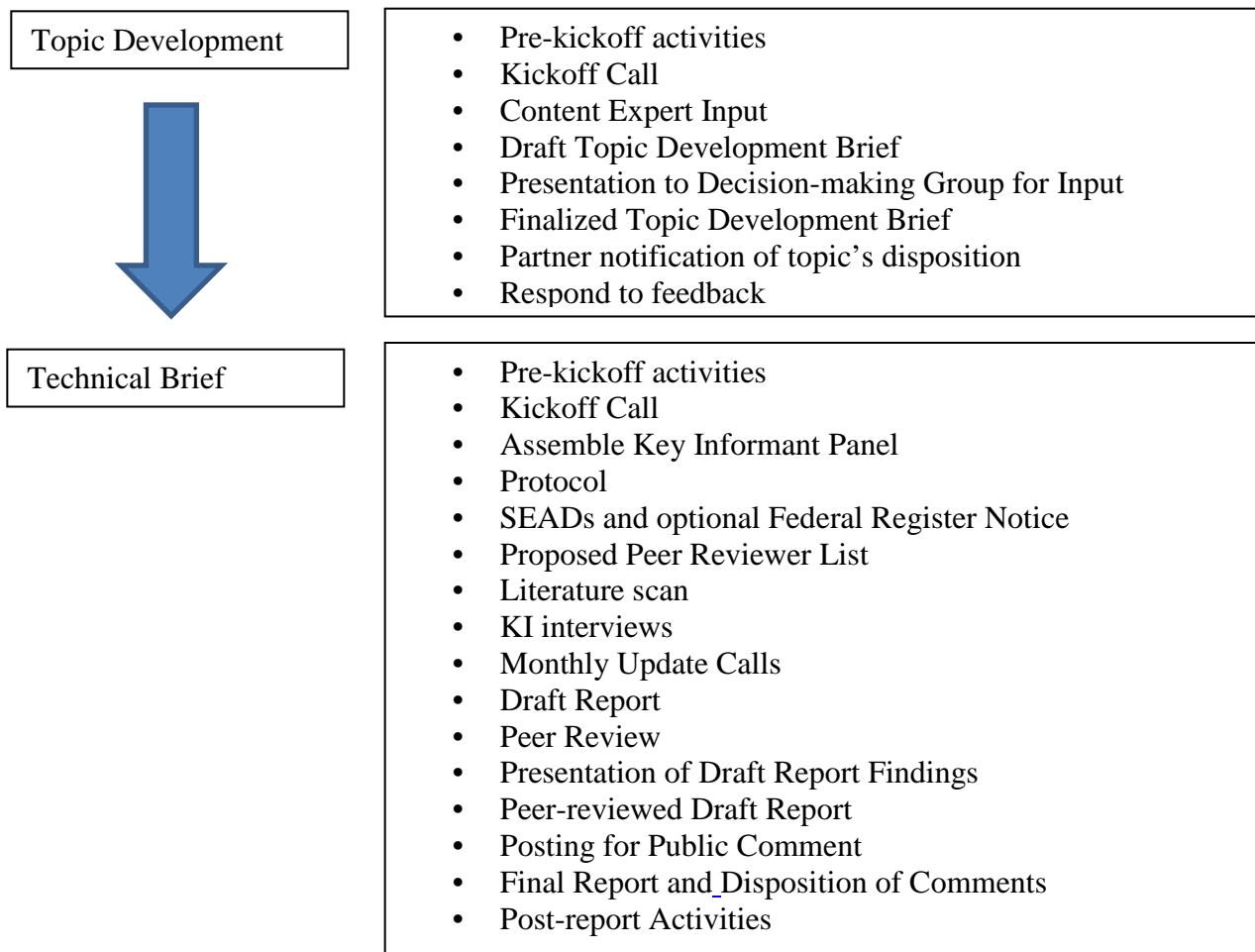
### *Overview: Systematic Review Update*

- Pre-Kickoff Call
- Kickoff Call
- Draft Protocol
- Assemble Technical Expert Panel
- 1st TEP Call
- Final Protocol and Posting
- SEADs and optional Federal Register Notice
- Literature Review
- Optional TEP Calls
- Monthly Update Calls
- Proposed Peer Reviewer List
- Preliminary list of included studies and mock-up of summary tables
- Draft Report
- Peer Review
- Presentation of Draft Report findings
- Peer-reviewed Draft Report (if sequential peer review and public comment)
- Post Draft Report for Public Comment
- Literature Update
- Final Report and Disposition of Comments
- Post-Report Activities

*Overview: Rapid Review*

- Pre-Kickoff Call
- Kickoff Call
- Protocol
- Literature Review
- Proposed Peer Reviewer List if peer review desired
- Draft Report
- Peer Review-optional
- Post Draft Report for Public Comment-optional
- Final Report and Disposition of Comments
- Presentation of Final Report findings
- Post-report Activities

*Overview: Topic Development and Technical Brief*



## **Process Details and Timelines**

### **A. Pre-Kickoff Call Activities**

For almost all EPC products, there are several required activities before the Kickoff call (*Ctrl + Click to follow links*):

1. [Partner Involvement](#)
2. [EPC Team Staffing Plan](#)
3. [Deliverable Schedule](#)
4. [EPC Team COI Disclosure and Confidentiality Forms](#)
5. [Proposed Key Informant \(KI\) and Technical Expert Panel \(TEP\) List](#)
6. [Pre-award posting of key questions for public comment](#)

#### **1. Partner Involvement**

*The EPC is not involved in this activity, but the information may be helpful as background.*

The TOO will set up a call with the Partner 1-3 weeks before the proposed kick-off call. Items to discuss on the call:

- Primary point of contact.
- Planned use of the deliverable
- Suggested end-users (patients/consumers, clinicians, policymakers, healthcare organizations, payers) who may be interested in this topic
- Dates of associated events and any hard deadlines for EPC deliverables
- Roles and responsibilities: As outlined in the “Partner Role Checklist”
- Points for Partner input
- Expectations for review or sharing of EPC materials.
- Timing of EPC presentations
- Default is during peer review
- For projects with sequential peer review and public comment, this presentation could instead occur during public comment
- Other outside activities for coordination
- Relationship with TOO:
  - The TOO is responsible for approval of all EPC deliverables.
  - The TOO is the primary point of contact (POC) for EPC and AHRQ.
  - The TOO should be included in all email communications between the EPC and Partner.
- Required forms
  - Partner checklist. Complete this before the call.
  - The TOO collects signed Confidentiality forms from Partner organizational representatives.

- The EPC will collect the usual confidentiality forms and COI forms from Partner representatives who will serve as a KI or TEP as described in the Combined Topic Refinement/Systematic Review (TR/SR) chapter.

## **2. Staffing Plan**

This document identifies key EPC staff working on the project. Briefly, personnel may include a principal investigator who oversees project management, scientific content and integrity, a project manager who is responsible for management, research associates who conducts the research and helps prepare the report, a research librarian, and clinical experts who provide clinical feedback.

**Resource:** Staffing plan templates and project management files are on the SRC Secure Site: Resources /EPC Process Resources/01. EPC Program Policies and Procedures/Work files and Contract Process forms.

## **3. Deliverable Schedule**

Within one week of the contract award date, the EPC must submit the project management file or deliverable schedule. This file lays out the timeline for the project and specific deliverables. The schedule varies by the type of project (topic development, topic refinement, technical brief, SR).

Sample project management/deliverable schedules are at the end of each Procedure Guide Chapter (as Word tables) or on the SRC Secure Site as .mpp files.

## **4. EPC Team Disclosure of Conflict of Interest (COI) Forms and Confidentiality Agreements**

For each individual who will assist in the project, the EPC must submit a signed COI Disclosure form and the EPC Team Confidentiality Agreement. To use the online COI form, contact the SRC. If necessary, the EPC must submit the plan for mitigation of any conflicts of interest.

The TOO must review all proposed staff and notify the EPC of approval (or objections) within one week after forms are received. Staff cannot participate in the project until approved.

The EPC shall maintain confidentiality on the findings of the project. The EPC cannot present or publish any findings until a final product is publicly available. The program has specific venues for solicited expert input through engagement of specific stakeholders or experts. The EPC shall refer any unsolicited inquiries or comments outside of these structured processes to the TOO.

**Resource:** “Disclosure Policy and Confidentiality Forms”. SRC secure Site: /EPC Process Resources/01. EPC Program Policies and Procedures/.

**5. Key Informant and Technical Expert Panel Lists** *(does not apply to Topic Development Briefs, Rapid Reviews, Rapid Response, or Surveillance pre-kickoff call)*

The PI of the project is responsible for assembling the lists of potential Key Informants (KIs) and Technical Expert Panel (TEP) members. KIs and TEP should be advised that, unless they opt out, they will be acknowledged by name in the final report.

**Resource:** SRC Secure Site: Resources/Stakeholder engagement/KIs.

**Resource:** Brochures on EPC Methods and Processes

<https://effectivehealthcare.ahrq.gov/topics/get-involved/synthesizing-evidence-brochure>

<https://effectivehealthcare.ahrq.gov/topics/get-involved/making-sure-brochure>

<https://effectivehealthcare.ahrq.gov/topics/get-involved/research-2018-2>

**i. Key Informants**

The EPC shall submit a list of five-nine individual KIs to the TOO. The Partner\* and TOO may suggest additional individuals. Depending on their expertise, some KIs may also serve on the TEP.

While the Partner has provided the initial topic and decisional issue prompting the review, KIs provide additional input to provide context and focus the review.

NOTE: The scope should narrow around the important decisional dilemmas and should not widen as the result of KI input. Specifically, the KIs may provide input on:

- Outcomes of particular importance to be graded
- Comparisons of interventions for which there is uncertainty, or multiple interventions that users must decide between
- Populations that should be considered distinct from one another when comparing interventions or tests, or population characteristics giving rise to controversy or uncertainty
- For technical briefs, patients could identify what features would be important to them from the proposed new technology/intervention and what their concerns would be.
- For technical briefs contextual detail about the use or perceptions of interventions or technology

For projects funded by the NIH Pathways to Prevention (**P2P**) program:

Instead of developing a list of Key Informants, the EPC will invite members of the NIH Office of Disease Prevention (ODP) Working Group. This Working Group is comprised of individuals from the ODP as well as the pertinent Institute/Center representatives.

**ii. Technical Expert Panel**

The EPC must submit a list of five to nine Technical Experts to the TOO before

the TEP call. The Partner and TOO may suggest additional individuals. TEPs may provide input to:

- Focus the literature search by identifying search terms and relevant grey literature.
- Identify inclusion/exclusion criteria to evaluate the quality of studies and rate the strength of the overall body of evidence
- Clarify specific methodologic or clinical issues that may arise.
- Identify specific subgroups that may have heterogeneity of treatment effect.
- Clarify KQs, PICOTS and proposed review methods

### **iii. OMB Guidance**

When organizing KI, TEP, or other stakeholder calls, the EPC must abide by the Paperwork Reduction Act (PRA), overseen by the Office of Management and Budget (OMB) (<http://www.hhs.gov/ocio/policy/collection/>):

- OMB approval is not required for informal information gathering from fewer than nine persons such as:
  - Open discussions of agenda items from focus group or expert panels, such as during an in-person meeting or conference call.
  - Free-form discussions with individuals.
  - Posting something for comment or inviting individuals to provide comment.
- The nine-person limit does not apply to U.S. federal government employees, or contractors within the EPC Program.
- When the EPC gathers information informally, it should describe this process in documents as “feedback” or “input,” and not as “consensus,” “results,” or “advice.”
- OMB approval is required to ask the same question of more than nine non-federal persons, including those from other countries. This may include:
  - Individual structured or semi-structured interviews.
  - Specific survey questions sent via paper, web, or email.
- Obtaining OMB approval can be a lengthy process and is therefore not ideal, given the tight time line for EPC Reports.

## **6. Pre-award posting of Key Questions for public comment**

This applies only to projects with topic refinement. For some projects, AHRQ may post the key questions for public comment during the pre-award phase rather than during topic refinement. In these instances, AHRQ will upload all comments to the Secure Site for the EPC to review. The EPC should consider these comments and provide a high-level summary of a response in the Topic Refinement Document Part 1.

**Resource:** Resources /EPC Process Resources /05. Topic Refinement /Topic Refinement Templates. TR Document 10.23.18



## **B. Post-Report Activities**

For almost all EPC products, there are several required activities after finalizing the EPC report (*Ctrl + Click to follow links*). These steps do not apply to topic development briefs.

1. [Systematic Review Data Repository \(SRDR\)](#)
2. [Feedback Form](#)
3. [AHRQ Publication/Posting on Website](#)
4. [Assist with translation and dissemination](#)
5. [Presentation and Abstract Submissions](#)
6. [Publication of a Manuscript in a Peer-Reviewed Journal](#)
7. [Third Party Press Releases](#)

### **1. [Systematic Review Data Repository \(SRDR\)](#)**

Data used in the completion of the final report shall be entered into SRDR using data extraction forms. This promotes searchability and re-use of data, which are made freely available to the public for download (through the SRDR at [www.srdr.ahrq.gov](http://www.srdr.ahrq.gov)) upon publication of the report. Upload of data in formats that cannot be accessed by SRDR's native search functions will be considered non-compliant. The EPC shall send an email to notify the TOO when the database has been uploaded and published within the SRDR.

**Resource:** SRC Secure Site: Resources /EPC Shared Resources and Samples /SRDR uploading

### **2. [Feedback Form](#)**

The EPC will complete a feedback form within one week after the Final Report is approved. Feedback is intended to identify issues encountered in the Systematic Review process. It will be used by the EPC Program to identify areas for improvement in program guidance and the Methods Guide. It is not used to evaluate TOOs or EPCs.

The link to the web-based feedback form will be available in each EPC project folder. Multiple users may enter and save data during the project. When the Final Report is accepted and all feedback has been entered, the EPC will submit the feedback form. All data will be stored in the SRC database. A PDF will be created for the TOO to review. When forms are completed, the system creates a PDF and stores it in the EPC folder on the Secure Site.

### **3. [AHRQ Publication/Posting on Website](#)**

**Editing:** AHRQ's Office of Communication (OC) will edit the Final Report. OC will email proposed edits to the EPC or SRC authors and cc the TOO. The report authors and OC should complete editing within six weeks of Final Report approval.

## *Post-Report Activities*

For the **TA Program**, the TOO serves as the final editor.

Posting: After editing, OC forwards AHRQ products to the AHRQ web team for posting on the EHC website.

**For the TA program**, the TOO sends the Final Report to CMS for posting on the CMS website. The AHRQ Web Team posts the CMS link to the report on the AHRQ TA webpage, next to the Disposition of Comments.

Acknowledgements: When the Final Report is posted, the EPC or SRC should thank the Key Informants and TEP members for their participation via email. Include a link to the Final Report in the email. The TOO will contact the Partner.

Posting of Disposition of Peer and Public Comments document for systematic reviews and technical briefs: Three months after the Final Report is posted, AHRQ will post the Disposition of TEP, Peer and Public Comments document on the EHC website.

### **Resources:**

For Guidance, Templates and Abbreviated Checklist for EHC Papers. SRC Secure Site: Resources /EPC Process Resources /02. Publishing Guidelines and Templates

AHRQ Publications and Communications Guidelines.

<https://www.ahrq.gov/research/publications/pubcomguide/index.html>

## **4. Assist with Translation and Dissemination**

AHRQ's OC may craft a dissemination plan for the evidence report with products or materials aimed at diverse audiences. The EPC or SRC and the TOO will be asked to provide input on the accuracy and framing of key messages from the final report.

## **5. Presentations and Abstract Submissions**

EPCs and the SRC are encouraged to present the findings of the project Report to scientific or non-scientific audiences. However, (except as required in the Task Order) presentations, slide decks on the final report, and abstracts are not required deliverables, and reimbursement is not included in the project budget.

Authors may submit abstracts before a Report is posted. The EPC or SRC must notify the TOO in advance of the planned abstract and conference date, and provide a copy of the abstract and conference information to the TOO when the abstract is submitted. However, authors must confine the presentation or abstract publication to publicly available findings. For example:

- Abstracts based on the Final Report must be withdrawn if the Final Report posting will occur after the presentation date.

To request AHRQ funding for a presentation, the EPC or SRC must submit a "Request

## *Post-Report Activities*

for Dissemination Support” to the TOO.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /01. EPC Program Policies and Procedures.

### **6. Publication of a Manuscript in a Peer- reviewed journal**

EPCs and SRC are encouraged to publish the findings of project reports in appropriate refereed scientific journals. However, unless specified in the Task Order, a journal manuscript is not a requirement or deliverable, and reimbursement is not included in the project budget.

Additionally, the EPC and SRC may not publish any manuscripts based on AHRQ-supported work before AHRQ has published the Final Report.

The EPC or SRC may submit a journal manuscript no earlier than the Draft Report is approved for Peer Review and public posting. Submitting at this stage increases the likelihood of co-publication (in the journal at the same time as the AHRQ publication) and avoids delays.

See resources for information about obtaining copyright assertion.

For NIH P2P projects, The EPC shall develop a manuscript publication that reflects the main findings of the publicly posted EPC report. The manuscript publication cannot occur before public posting of the final AHRQ report. Communicate with the AHRQ TOO and OC Editor to facilitate simultaneous release of the manuscript publication, the AHRQ report, the P2P workshop report and any additional workshop-related manuscripts.

#### **Resources:**

Roles and Responsibilities of EPC and AHRQ for Journal Co-publication Resources /EPC Process Resources /01. EPC Program Policies and Procedures /Journal Co-publication Resources

Getting recognition for your AHRQ-funded study Resources /EPC Process Resources /01. EPC Program Policies and Procedures /Journal Co-publication Resources

### **7. Third Party Press Releases**

In addition to AHRQ’s dissemination plans, an EPC’s organization, the SRC, or the Partner may wish to create its own press release. If so, the organizational contact, report authors, TOO, and OC media relation staff must work together. At minimum:

- The press release must acknowledge AHRQ sponsorship.
- AHRQ must approve the press release.
- The press release cannot precede AHRQ’s press release.
- If the press release includes a quote from a Federal spokesperson, it must go through ASPA (DHHS Assistance Secretary for Public Affairs) clearance.

**Resource:** Additional information is in AHRQ’s Publishing and Communications Guidelines. <https://www.ahrq.gov/research/publications/pubcomguide/index.html>.

## C. Topic Development Brief

### Overview of key process steps

(Ctrl + Click to follow links)

1. [Pre-Kickoff Call Activities](#)
2. [Kickoff Call](#)
3. [Content Expert Input](#)
4. Draft [Topic Development Brief](#)
5. [Present to Decision-making Group for Input](#)
6. [Finalize Topic Development Brief](#)
7. [Notify Partner of Topic's Disposition](#)
8. Respond to [Feedback](#)

### 1. Topic Development Brief:

The goal of Topic Development Brief is to explore and scope a general topic or question for further action (e.g., production of a Systematic review or Technical brief or for further research). The EPC will identify the key decisional dilemma and clinical and/or policy context surrounding the topic nomination, evaluate its fit against established criteria, and summarize this information in a Topic Development Brief. The EPC will present the Topic Development Brief to a decision-making group for discussion. This group will determine whether the topic should go forward for further action, depending upon program resources and priorities. The EPC then will finalize the Topic Development Brief.

A Federal agency may request Topic Development Briefs through an IAA to inform their own decisions about selection and prioritization, such as program priorities and research gaps funding. For these projects, the Sponsoring Partner provides the topics and selection criteria, and convenes and manages the decision-making panel. Final Topic Development Briefs are submitted to the TOO and Sponsoring Partner.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /04. Topic Development /Background and Resource Documents

### 2. Topic Development Brief Process Steps

1. [Pre-Kickoff call.](#) (See [Chapter A](#))

#### 2. [Kickoff Call](#)

The EPC will convene a conference call with the TOO (and Sponsoring Partner, if IAA). Upon award, the TOO will inform the EPC of optional participants, including other AHRQ staff or individuals involved in the project. The purpose of the Kickoff call is to:

- Discuss purpose of requested project and identify the decisional dilemma(s).
- Review elements of work to be performed.

## *Topic Development Brief*

- Describe a plan for developing topic brief.
- Establish lines of communication between the EPC, TOO, stakeholders, other AHRQ staff, and partners.
- For IAAs:
  - Introduce the Sponsoring Partner expectations
  - Clarify the selection criteria and format to meet the needs of the Sponsoring Partner
  - The EPC should copy the TOO on all email communications Sponsoring Partners and nominators. In the rare occasion that the TOO cannot attend a call between the EPC and Sponsoring Partner, the EPC must send a written call summary to the TOO.

### **3. Content Expert Input**

The EPC must gather input from local clinical experts (including primary care providers and specialists), the nominator, Sponsoring Partners, or other stakeholders readily available to the EPC. The purpose of these discussions is to gather background so that topic development is responsive to the decisional needs of stakeholders.

Discussions are to be limited and efficient. The EPC will use this input to understand aspects of the topic such as practice variation, clinical uncertainty, appropriate comparators, and important subpopulations. For broad nominations, the topic development team may need to focus on areas of greatest importance and relevance to stakeholders. If the proposed evidence review will be used to develop guidelines, it is helpful to know the areas of greatest uncertainty and the timeline.

Since discussions are limited and for the purpose of background, individuals do not need to submit COI disclosure forms or be approved by the TOO.

### **4. Draft Topic Development Brief**

The EPC will complete a Topic Development Brief (see Resources for templates). The format of Topic Development Briefs and the selection criteria may vary for projects with a Sponsoring Partner. In general, the Topic Development Brief includes:

- Summary of nomination and decisional dilemma(s), with preliminary Key Questions and PICOTS
- Preliminary assessment of available literature and pre-specified selection criteria
- Proposed disposition with code and rationale
- Considerations for discussion, if any

#### **Resources:**

General guidance. SRC Secure Site: Resources/EPC Process Resources/01. EPC Program Policies and Procedures.

Examples and Templates: SRC Secure Site: Resources/EPC Process Resources/04. Topic

## *Topic Development Brief*

Development.

### **5. Present to Decision-making Group for Input**

The EPC will present the Topic Development Brief to the decision-making group. The purpose of this 2-5 minute presentation is to summarize the scope and proposed disposition of the nomination.

#### **Resource:**

Topic Triage Presentations. SRC Secure Site: Resources /EPC Process Resources /04. Topic Development /Process Documents

The decision-making group will vote on the disposition of the Topic Development Brief. The composition and management of the decision-making group depends on the source of funding:

- For the EPC program, the decision-making group includes individuals from AHRQ and the SRC. The SRC manages the logistics for topic selection meetings and tracking of nominations, topic briefs, and dispositions. The SRC will distribute Topic Development Briefs to the topic selection group prior to each meeting.
- For an IAA, the Sponsoring Partner will choose and convene the decision-making group. The Partner manages meeting logistics, and the TOO will send the Topic Development Briefs to the Partner to distribute to the selection group.

### **6. Finalize Topic Development Brief**

After the topic selection discussion, the SRC will prepare minutes of the meetings.

The EPC will finalize the Topic Development Brief with a summary of the discussion and clear rationale for the final disposition. The EPC will upload this Final Topic Development Brief (with the disposition and meeting summary incorporated) to the Secure Site. The TOO will review and approve this document.

### **7. Notify the Partner**

For the EPC Program, the SRC will send the approved Final Topic Development Brief to the nominator and AHRQ. The AHRQ web team will post the Final Topic Development Brief on the EHC website.

For IAAs, the Sponsoring Partner may also review the Final Topic Development Brief, as delineated in the Sponsor Checklist. After approval by the TOO, the TOO will send the approved Final Topic Development Brief to the Sponsoring Partner. These are not posted on the EHC Web site.

#### **Resource:**

Each project's Partner Checklist is located in the project folder on the Secure Site.

## *Topic Development Brief*

### **8. Responding to Feedback**

Responding to feedback generated by Topic Development Briefs helps to ensure that the EPC Program is responsive to the initial nomination and that all decisions are transparent. If anyone sends a comment or question concerning a Final Topic Development Brief, the brief's authors will draft a response to be reviewed by the TOO. For IAAs, the Sponsoring Partner handles feedback.

### **3. Topic Development Brief Deliverables**

**Table C. Sample Topic Development Brief Deliverable Schedule**

The Task Order Officer (TOO) reviews deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. Note: an abbreviated version of this timeline is included in contract documents.

<b>Task/Deliverable</b>	<b>Recipient</b>	<b>Weeks from Award</b>
Staffing plan, project management file/schedule of deliverables	Secure Site	1
For each EPC staff: COI form, confidentiality form, mitigation plan if needed	Secure Site	2
Kickoff Call summary	Call participants	3
Draft Topic Development Brief	Secure Site, notify TOO	7
Present Topic Development Brief	Decision-making Group meeting	8 or more
Final Topic Development Brief	Secure Site, notify TOO	2 weeks after Decision-making Group meeting

### **D. Combined Topic Refinement and Systematic Review**

#### **Overview of key process steps for Combined TR/SR in chronologic order**

*(Ctrl + Click to follow links)*

1. [Pre-kickoff Call Activities](#)
2. [Kickoff Call](#)
3. [Assemble Key Informant Panel](#)
4. [Topic Refinement, Part 1 Preliminary Scope](#)
5. [KI Calls](#)
6. [Topic Refinement, Parts 2 and 3](#)
7. [Post KQ Posting Document for Public Comment](#)
  - CONTRACT OPTION
8. [KQ comments call](#)
9. [Draft Protocol](#)
  - SR CONTRACT BEGINS
10. [Assemble Technical Expert Panel](#)
11. [1st TEP Call](#)
12. [Final Protocol and Posting](#)
13. [SEADs Portal and optional Federal Register Notice](#)
14. [Literature Review](#)
15. [Optional TEP Calls](#)
16. [Monthly Update Calls](#)
17. [Proposed Peer Reviewer List](#)
18. [Preliminary list of included studies and mock-up of summary tables](#)
19. [Draft Report](#)
20. [Peer Review](#)
21. [Draft Report Presentation to Partner and TEP](#)
22. [Peer-reviewed Draft Report \(if sequential peer review and public comment\)](#)
23. [Post Draft Report for Public Comment](#)
24. [Literature Update](#)
25. [Final Report and Disposition of Comments](#)
26. [Post-report activities](#)



## ***Combined Topic Refinement and Systematic Review***

### **1. Overview of combined Topic Refinement and Systematic Review:**

Most EPC Systematic Reviews include Topic Refinement, and this chapter outlines the Topic Refinement process steps and deliverables.

Optional steps are in italics. Bold type or asterisks indicate differences in processes for CMS Technology Assessment (TA) or NIH P2P programs

### **2. Combined TR/SR Process Steps:**

#### **1. Pre-kick-off call activities** (See [Chapter A](#))

- a. Partner Involvement
- b. EPC Team Staffing Plan
- c. Deliverable schedule
- d. EPC Team COI Disclosure and Confidentiality Forms
- e. Proposed Key Informant (KI) and Technical Expert Panel (TEP) List

#### **2. Kickoff Call**

The EPC must lead a conference call with the TOO and Partner, in order to:

- Introduce and discuss roles of the Partner
- Discuss partner's planned use of the report and the dates of associated events and any hard deadlines for EPC deliverables.
- Review decisional dilemmas and the elements of work to be performed, such as any presentations or webinars.
- Review list of proposed Key Informants and Technical Experts
- Discuss presentation of Draft Report findings.
  - If the project has sequential peer review and public comment, discuss whether the presentation will occur during peer review or public comment
- Describe a plan to engage Key Informants and Technical Experts
- Review role of Associate Editor, and EPC preferences about the AE role. See Resources about AE role on the Secure Site.
- Establish lines of communication between the EPC, TOO, stakeholders, other AHRQ staff, and Partner(s), including professional organizations and the United States Preventive Services Task Force (USPSTF) or other Federal Partners.
- Poll for availability and set up Monthly Call schedule

**Resource:** Each project's Partner Checklist is located in the project folder on the Secure Site.

AE role: SRC Secure Site: Resources /ScholarOne (formerly Manuscript Central) /AE Training Materials

#### **3. Assemble the Key Informant (KI) panel**

**NOTE:** The Pre-Kickoff Call ([Chapter A](#)) covers development of the KI list.

**Recruitment:** After the kick-off call, the EPC must recruit KIs and obtain CVs, signed

## ***Combined Topic Refinement and Systematic Review***

COI Disclosure forms, and Confidentiality agreements. TOOs can waive the CV requirement for patients or similar participants without readily available CVs. The EPC should advise the KIs that, unless they opt out, the final Systematic Review will acknowledge them by name. Recruitment of KIs can be challenging.

Manage Conflict of Interest (COI) Disclosure: The PI should review the COI Disclosure forms for potential financial or non-financial conflicts of interest. If a COI is identified, the PI must submit a rationale for including this individual to the TOO for discussion with the EPC Program director.

Approval: The TOO should acknowledge acceptance of the COI Disclosure forms (and rationale) within 1 week. KIs may not serve until they have been approved by the TOO.

**Resource:** “Disclosure Policy and Confidentiality Forms”. SRC Secure Site: Resources /EPC Process Resources/01. EPC Program Policies and Procedures/.

### **4. Topic Refinement Document, Part 1 Preliminary Scope**

Topic Refinement focuses the scope, Key Questions and PICOTS so the Systematic Review addresses the key stakeholder decisional dilemma(s). Topic Refinement results in three process documents (Part 1: Preliminary Scope; Part 2: Draft Scope, and Part 3: KQ Posting Document) and the Draft Research Protocol for a new Systematic Review.

Before the KI call, the EPC prepares Part 1: Decisional dilemma and Preliminary Scope. This includes the decisional dilemma(s), background and clinical context; clarifies the preliminary Key Questions, PICOTS, and analytic framework; outlines the quantity, quality, and challenges of the literature base; and describes key issues for additional input from Key Informant discussions. To complete Part 1, the EPC will scan the scientific literature in a targeted manner to assess the scope of the topic.

If the KQ were posted pre-award, the TR part 1 document shall include a high level response to public comments.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /05. Topic Refinement /Topic Refinement Templates.

### **5. KI Calls**

The EPC must schedule and lead all KI calls. Participants include the TOO, Partner, the KIs. Prior to the calls, the EPC should provide Part 1: Preliminary Scope to KIs at least one week in advance.

KI calls gather input on appropriateness of the Key Questions, PICOTS and analytic framework to address the identified key decisional dilemma(s). The EPC shall engage Key Informants to further refine the scope of the questions and further clarify the key decisional dilemmas. This process should narrow the scope of the review rather than broaden it.

## **Combined Topic Refinement and Systematic Review**

To meet the scheduling needs of KIs and to address the topic adequately, the EPC may need several calls. The EPC should consider holding the patient or consumer call separately, since patients or consumers may find it difficult to express their views if scientific experts dominate the call.

If the KIs and Partners have differing views, the reason for these differences should be explored and discussed with the TOO. In general, the perspective of the Partner should guide the review, since they will be using the final report.

NOTE: For the **NIH P2P program**, instead of the KI call, the EPC presents the Topic Refinement Document Part 1 to the NIH Working group via webinar. This presentation will require PowerPoint slides.

**Resources:** SRC Secure Site: Resources/Stakeholder engagement.

Brochures on EPC Methods and Processes:

<https://effectivehealthcare.ahrq.gov/topics/get-involved/synthesizing-evidence-brochure>

<https://effectivehealthcare.ahrq.gov/topics/get-involved/making-sure-brochure>

<https://effectivehealthcare.ahrq.gov/topics/get-involved/research-2018-2>

### **6. Topic Refinement Document, Parts 2 and 3**

**Part 2: Draft Scope:** After the KI calls, the EPC develops Part 2: Draft Scope. This internal document between AHRQ and the EPC is a high-level summary of KI input, including an updated literature scan (if undertaken); changes to the KQ, analytic framework and/or PICOTS; and the rationale for these changes. It may include discussion of controversial issues or differing opinions, especially between the Partner and KI.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /05. Topic Refinement /Topic Refinement Templates.

**Part 3: KQ Posting Document:** After the KI calls, the EPC develops Part 3: Key Question Posting Document. This document contains the draft Key Questions, PICOTS, a succinct description of the important decisional dilemma(s), and draft analytic framework that resulted from the KI calls. The TOO will review and route for EPC Program leadership review. When approved, the TOO will route for EHC website posting.

This is not required if the key questions have been posted for public comment during the pre-award phase.

If applicable contractually, this marks the point when AHRQ may exercise the Systematic Review option. The TOO will consult with the EPC and AHRQ EPC program leadership before exercising the option.

NIH **P2P** projects do not publicly post the KQ Posting Document.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /05. Topic Refinement /Topic Refinement Templates.

## **Combined Topic Refinement and Systematic Review**

### **7. Post KQ document for Public Comment \***

To solicit public comment, the KQ Posting Document will be posted to the EHC website for 3 weeks. If specified in the TO, a Sponsoring Partner may opt out of this posting.

The EPC should e-mail the link to the KQ Posting Document to the KIs, thank them for their participation and invite them to comment via the public review process. The TOO will email the link to the KQ Posting Document to the Partner's organizational representatives.

If anyone contacts the EPC directly about the KQ Posting Document, the EPC should refer them to the TOO and request that comments be provided via the public review process.

At the end of the public posting period, the EPC Program coordinator will upload public comments to the Secure Site and notify the TOO, who will then notify the EPC. For most projects, the EPC will include a response to public comments in the Draft Protocol.

\*This is not needed when the Key Questions have been posted for public comment during the pre-award phase. In this case, the EPC will include a response to public comments in the TR part 1 document.

For the **TA** program, public comment is 2 weeks.

**P2P** projects do not post KQ for public comment.

### **8. KQ Comments Call**

The purpose of this call is to discuss integrating public comments and suggested edits into the KQ, PICOTS, Protocol and/or proposed TEP list; and to flag any issues for the draft protocol. *A KQ comments call is optional.*

- For the **TA program** the EPC is required to: Develop a Disposition of Comments Document, and submit to the TOO and CMS project staff prior to the comments call. This disposition is an internal document. AHRQ will not publically post this disposition.
- Revise the KQ posting document after the comments call, incorporating changes in the KQ and PICOTS. This will be posted on the AHRQ TA webpage.

**Resource:** SRC Secure Site: Resources /Technology Assessment Program /TAPTemplates and Procedures.

### **9. Draft Protocol**

The final deliverable of the Topic Refinement task order is the Draft Research Protocol (Draft Protocol). The EPC will develop the Draft Protocol using the Protocol Content Guidance. If the Key Questions have significantly changed in response to public input,

## **Combined Topic Refinement and Systematic Review**

the EPC may conduct an exploratory literature search to ensure a manageable scope.

The EPC will submit the Draft Protocol to the TOO, who will review for accuracy and consistency with guidance, and route for EPC Program leadership review. *Optional: the EPC or TOO may request AE review, concurrent with the TOO review. The TOO should clarify and resolve feedback with the AE prior to sending comments to the EPC.*

Contractually, this point marks the beginning of the SR option, if awarded. If changes are needed, the EPC must update the staffing plan and deliverable schedule.

For **NIH P2P** projects, EPC will present the draft protocol via webinar at an ODP Content Area Experts meeting. The Content Area Experts and members of the NIH ODP Working Group may provide comments during this meeting. This meeting is separate from the Technical Expert Panel call, but will occur approximately the same week as the Technical Expert Panel call. A draft and final version of the draft protocol presentation PowerPoint slides will be due prior to the presentation.

**Resources:** for template and guidance: SRC Secure Site: Resources /EPC Process Resources /08. Systematic Review Protocol).

### **10. Assemble the Technical Expert Panel (TEP)**

The EPC must submit a list of five-nine Technical Experts (TE) to the TOO before the TEP call. The Pre-Kickoff Call section covers development of the TE list.

Recruitment: the EPC must recruit stakeholders and obtain CVs, signed COI Disclosure forms, and Confidentiality agreements. The EPC should advise the TEP that, unless they opt out, their names/contact information will be shared with the SRC for potential future consultation, and that they will be acknowledged by name in the Systematic Review.

Manage Conflict of Interest (COI) Disclosure: The PI should review the COI Disclosure forms for potential financial or non-financial conflicts of interest. The PI must submit a rationale to include any individual with disclosed COI. The TOO will discuss the agency response—including mitigation plans—with the EPC Program director.

Approval: The TOO should approve the COI Disclosure forms (and mitigation plan) within one week. TEPs may not serve until they have been approved by the TOO.

### **11. First TEP Call**

The EPC must schedule and lead all TEP calls. Participants include the EPC, TOO, and the TEP. The EPC should provide the Draft Protocol to participants at least 1-2 weeks before the call. The TEP may provide input on KQs, PICOTS, critical outcomes to be graded, data sources and search strategy, key studies to be included, or minimally important differences for particular outcomes. See Pre-Kickoff Call Chapter A for additional TEP description.

For **NIH P2P** projects, the Technical Expert Panel call should occur approximately the

## **Combined Topic Refinement and Systematic Review**

same week as the Content Area Experts meeting.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /09. Technical Expert Panel (TEP)

### **12. Final Protocol and Posting**

The EPC must revise the Draft Protocol to reflect discussions with the TEP, and submit the Final Protocol. The TOO will review for accuracy and consistency with guidance, and route for EPC Program leadership review. The TOO will notify the EPC when the Protocol is posted. The EPC will send a copy of the link to the TEP, and KIs. The TOO will notify the Partner of the Protocol posting. The EPC will register the Final Protocol in the PROSPERO database (<http://www.crd.york.ac.uk/prospero/>).

Changes to a posted Final Protocol require a Protocol amendment, which entails making the necessary edits and summarizing the changes made along with the rationale. The Protocol template has a section for amendments.

The **TA Program** posts the final protocol to the AHRQ TA program webpage.

For NIH **P2P** projects, the posted final protocol should not refer to the NIH P2P program.

### **13. Supplemental Evidence and Data for Systematic Reviews (SEADS) and Federal Register Notice**

At Final Protocol posting, AHRQ will notify the public about a SEADS portal through the EHC listserv. The SEADS portal is open for 4 weeks, and AHRQ will upload any materials received to the project folder on the Secure Site.

For the EPC Program, the decision for a Federal Register notice will be made by the EPC and TOO. Reports that include medical devices, generic drugs, or poorly defined interventions (such as non-drug, health delivery interventions) require Federal Register notice.

Since creating a Federal Register Notice requires several approvals, notify the EPC Program coordinator of the intent as early as possible. The EPC Program coordinator will initiate and manage this notice, and will notify the EPC and TOO when the notice is posted.

The **TA Program** always posts Federal Register notices unless determined unnecessary by AHRQ and CMS staff. In such cases, the TOO will notify the EPC Program coordinator.

### **14. Literature Review**

The EPC must systematically search, abstract, review and analyze the scientific evidence for each Key Question as outlined in the EPC Methods Guide. Training modules are also available.

## **Combined Topic Refinement and Systematic Review**

**Resource:** Methods Guide for Effectiveness and Comparative Effectiveness Reviews  
<https://effectivehealthcare.ahrq.gov/topics/ceer-methods-guide/overview/> .

### **15. Additional TEP Input (optional)**

*During the literature review, the EPC or the TOO may request additional TEP input via a call or group email. The EPC should contact the entire TEP rather than individual members unless very specific expertise is required (e.g., statistician, member is author of a study in question, etc.) The TEP should not review the data, or be involved in data analyses.*

### **16. Monthly Conference Calls and Summaries**

After the first TEP Call, the EPC must summarize progress in monthly conference calls with the TOO. Call frequency may be adjusted, depending on issues that arise, and as requested by the TOO or EPC. The TOO may request that the agenda include attachments of working documents, such as reference lists, literature retrieval figures, draft summary tables, etc. Within one week after the call, the EPC must submit a summary of the call that describes progress, any problems encountered and their resolution, any foreseeable problems, and any expected change to the delivery schedule. The EPC upload the document to the Secure Site after the monthly call summary is approved by the TOO.

### **17. Proposed Peer Reviewer List**

The Peer Review Process is a collaborative process involving the EPC, TOO, and SRC. The EPC will identify potential peer reviewers and discuss them with the TOO and the partner. The SRC will manage the peer review invitation and collection of COI Disclosure and confidentiality forms through ScholarOne.

Three months prior to the Draft Report due date, the SRC will remind the EPC to upload the proposed peer reviewer list to ScholarOne. To assist the SRC in recruiting diverse perspectives to the final peer review panel, the list should include:

- Four to six first choice Peer Reviewers
- Eight to 10 alternate Peer Reviewers (invited only if first choice reviewers decline)
- All TEP members (clearly identified, as they are not Peer Reviewers)

The SRC will send the invitation letter to the peer reviewers and TEP, and copy the TOO. After initial recruitment of Peer Reviewers, the TOO will review COI disclosures of the reviewers to assemble a balanced peer review panel.

For each Draft Report, the goal is four independent and unbiased peer reviewers who agree to participate, with an appropriate mix of expertise and perspectives. To achieve this, the TOO may add names of peer reviewers (including other federal agencies and statistical/methods experts) before approving the final Peer Reviewer panel.



## ***Combined Topic Refinement and Systematic Review***

The SRC will direct individuals not selected as peer reviewers to comment via the public website.

**Resources:** Guidance and example are found on SRC Secure Site: Resources /ScholarOne (formerly Manuscript Central) /EPC Author Training Materials

### **18. Preliminary list of included studies and mock-up of summary tables for systematic review**

After full-text review, the EPC shall submit a preliminary list of included studies, with the understanding that changes may occur with data abstraction. The EPC will also submit a mock-up of summary tables; these may also change with data abstraction. While preliminary, this should inform a discussion with the TOO about organization and presentation in the final report.

### **19. Draft Report**

The EPC must submit the draft Systematic Review (Draft Report) and appendices via ScholarOne. Draft Reports are expected to be complete and of the same quality as a Final Report for effective peer and public review. If the Draft report fails to meet a minimal standard (as outlined below), the report will be returned to the EPC and the submission will not be considered as meeting required deadlines. The EPC editor and the EPC Director or Associate Director must review the Draft Report and attest to its integrity and quality before submission to AHRQ.

ScholarOne is used for submission and management of report revisions and peer review.

There are two potential review pathways for most EPC reports: simultaneous peer review and public comment, or sequential peer review followed by public comment. With both processes, an Associate Editor (AE) and TOO will review the Draft report.

If Peer and Public Review are simultaneous, detailed AE and TOO comments will be provided prior to any external review, and EPCs may be directed to make some revisions prior to release of the report for external review.

If peer and public review are sequential, the TOO will provide a rapid assessment of the report, and will approve it for external review if the report has:

- No missing sections of report (including appendices, incomplete tables, appropriate disclaimers)
- Consistency among Key Messages, key points (for each KQ) and conclusions
- Summary tables support Key Points (no errors)
- No bias in tone
  - Background does not appear to include conclusions for key questions
  - Does not include clinical recommendations based on review findings

The AE and TOO will then provide detailed comments during Peer Review (which the EPC shall address prior to Public Review).



## ***Combined Topic Refinement and Systematic Review***

If the AE and TOO do not agree on comments, they will resolve these differences prior to decision letter to the EPC. They may consult with the AHRQ EPC Program Director if needed. The EPC will receive notice of the AE and TOO decision (through ScholarOne) as follows:

- A. Accept (no revisions needed before Peer Review). The TOO will route the draft report for public posting and Peer Review. The decision letter may indicate minor revisions that should be addressed in the Final Report.
- B. Conditional Acceptance (minor revisions needed before Peer Review). The AE and TOO agree that the report clearly presents its main messages. Revisions are not substantive. The decision letter will indicate which revisions must be made before Peer/Public Review, and may include additional revisions that could be addressed in the Final Report, and a due date for the revision. The EPC will submit a revised Draft Report.
- C. Revise and Resubmit (major revisions are needed before Peer Review). The decision letter will distinguish which comments are major and minor issues and indicate the due date for the revised Draft Report.
  1. Letter only: Changes addressed prior to peer review may include inconsistencies within a report, non-adherence to accepted Methods Guidance, unclear descriptions of methods, or inadequate analyses or address of scope of questions.
  2. Requires call: Reports that fall in this category appear to be unclear, unfocused, or significantly flawed methodologically. The decision letter will propose a call to discuss major issues. The TOO will schedule a call with the AE and EPC within 2 weeks to resolve major issues and proposed revisions.

If the EPC disagrees with requested revisions, they should schedule a call with the TOO and AE within 1 week of receiving the comments. If the disagreement cannot be resolved, the EPC should email the AE and TOO, explaining the disagreement. The TOO will review before forwarding to the EPC Program Director. The EPC Program Director may then request input from an unconflicted external content, statistical, or methods expert prior to making a determination. The TOO will communicate the final decision to the EPC.

The EPC must document how AE and TOO comments were addressed in an “Author Response” document (see examples in [Resources](#)), and upload with Report revisions.

The EPC should consider submitting a journal manuscript when the Draft Report has been approved for Peer Review. Submission at this time increases the likelihood of co-publication and avoids delays posting the final report.

For the **TA Program**, AHRQ’s TA Program Director and CMS Project Staff will function as the AE.

## ***Combined Topic Refinement and Systematic Review***

Reports for the **NIH P2P** program will have sequential peer review and public comment.

**Resources:** Content Guidance: SRC Secure Site: Resources /EPC Process Resources /10. CER Content Guidance (Report and ES). The required template is SRC: Resources /EPC Process Resources /02. Publishing Guidelines and Templates.

Author instructions: Scholar One site: <https://mc.manuscriptcentral.com/ehc>. Also found at SRC Secure Site: Resources /ScholarOne (formerly Manuscript Central) /EPC Author Training Materials

### **20. Peer Review of Draft Report**

The SRC will manage Peer Review through ScholarOne. The goal is to have at least two submitted Peer Reviews by the close of the Peer Review period. If the required expertise is represented across peer reviewers and TEP reviewers, the TOO should not extend Peer Review unless absolutely necessary, such as in the rare instance when no peer reviewers have submitted comments.

The SRC will forward unedited Peer Review comments to the EPC as they are received. At the close of Peer Review, the SRC will deliver all comments to the EPC. The SRC will also upload comments to the Secure Site. Comments received after Peer Review ends will not be considered.

### **21. Presentation of Report Findings to Partners and KI/TEP**

**For the EPC Program.** The EPC shall present the findings from the draft report. Participants may include the partner, KIs and TEP. The EPC should invite a representative from the AHRQ Office of Communication. The EPC should send a copy of materials to TOO before the presentation and send a summary of the presentation discussion to the TOO and call participants after the presentation.

If the project has sequential Peer and Public Review, the Partner may elect to have this presentation during the public comment period, rather than during Peer Review.

**For the TA program.** The EPC must present the findings of the report to CMS at Evidence Forum and if applicable at the MEDCAC meeting. The EPC may be requested to present findings of the Final Report rather than the Draft Report. This may be presented via webinar or in person. If presentation in person is requested, CMS would arrange travel with the EPC directly. CMS Project Staff will set the timing of these meetings. For specific details about format, content, and timing consult the TOO.

**For the NIH P2P program.** The EPC shall present the findings from the peer-reviewed Draft Report at an in-person 2-day workshop in Bethesda, MD. The PI and methodologist should present the findings. A draft and final version of the PowerPoint slides will be due prior to the presentation as specified in the delivery schedule. This should not require the development of new content, and the preparation time should be limited to the time it takes to create the slides. Public comment will begin on the first day of the workshop.

## ***Combined Topic Refinement and Systematic Review***

**Resource:** Sample TEP presentation at Resources /EPC Process Resources /09. Technical Expert Panel (TEP) /TEP/KI mid-peer review webinar examples.

### **22. Peer-reviewed Draft Report**

For reports with sequential Peer Review and public comment, the Draft Report will be revised in response to comments from peer reviewers, AE and TOO. The EPC will submit a peer-reviewed Draft Report and disposition of Peer Review comments in ScholarOne.

All peer review/public comment on **NIH Pathways to Prevention (P2P) program** reports will be sequential. EPCs will present findings from the peer-reviewed Draft Report at the P2P workshop.

**Resources:** Same as for Draft Report plus:

Disposition of comments: SRC Secure Site: Resources /EPC Process Resources /12.  
Disposition of Comments

### **23. Posting of Draft Report for Public Comment**

When the Draft Report is posted for Public Review, the EPC should e-mail the Key Informants, and TEP members who declined to review the Draft Report, thank them for their participation, and invite them to comment on the report via the Public comment process (include the Draft Report link on the EHC Web site). The TOO will email the Draft Report link to any non-sponsoring Partner.

Public comments are submitted to the EHC website portal or EPC email. At the end of the Public comment period, EPC Program Coordinator uploads them to the Secure Site and notifies the TOO. The SRC uploads the comments to ScholarOne.

If anyone contacts the EPC to discuss the report, the EPC should refer the individual to the TOO and request that comments be provided via the public comment mechanism on the EHC site.

For the **NIH P2P** program, the revised version of the peer-reviewed Draft Report is publicly posted for comments for 4 weeks beginning on the first day of the **P2P** workshop.

**TA Program** Draft Reports are posted for 3 weeks on the AHRQ TA Program website. Comments are emailed to the EPC mailbox.

### **24. Literature Update**

The EPC must update the literature search during public comment period using the original search strategy to ensure that the search is current (i.e., less than 3 months old when the Final Report is anticipated to be accepted by AHRQ). The EPC must discuss the findings with the TOO and incorporate the findings into the Final Report.

## **Combined Topic Refinement and Systematic Review**

### **25. Final Report and Disposition of Comments**

After confirming with the TOO, the SRC notifies the EPC that the peer review period has ended via an email from ScholarOne. With concurrent Peer and Public Review, this email will include all comments from peer reviewers, TEP, and from the public. When Peer Review precedes Public Review, the SRC will send email with all comments from peer reviewers at the conclusion of Peer Review and will send all public comments after the end of Public Review.

*Optional: For responses to both Peer and Public Review, the EPC may hold a call with the TOO to discuss proposed approaches. EPCs should document this call in the Author Response document and submit it with the Final Report.*

The EPC must submit the Final Report. The Final Report includes updated research findings based on results of the updated search and comments from TEP, peer reviewers and the public. In addition, the EPC must submit the Disposition of Comments (from TEP, peer reviewers and the public), and an Author Response document (resolution of AE, TOO, and EPC Program leadership comments). The EPC must also submit the PRISMA checklist and alternate text for all figures.

The Final Report approval process is the same as that outlined for the Draft Report with the following addition:

If no resolution about disagreements about the report between the EPC and AHRQ can be made with 3<sup>rd</sup> party review, AHRQ will not prohibit publication and will post the Final Report on the EHC website after 6 months (with the appropriate disclaimer that is contained in Section H.1.b.2.B of the EPC contract). The TOO will communicate this decision to the EPC.

When the Final Report is approved in ScholarOne, the SRC will send EPC Authorship Forms for each author to complete in ScholarOne.

Partner Coordination: After approval and before publication of the Final Report, the TOO will contact the Partner about the timing of posting and any planned manuscripts. The TOO may share an electronic copy of the pre-publication Final Report with the Partner only after the TOO has received a signed non-disclosure agreement form from the Partner. The EPC must NOT share the pre-publication Final Report with the Partner.

For the **TA Program**, the TA Program Director and CMS Project Staff will function as the AE and review the Final Report.

Final **P2P reports** may be revised in response to public comments. The disposition of comments table will be updated to include public comments.

**Resources:** Same as for Draft Report plus:

Disposition of comments: SRC Secure Site: Resources /EPC Process Resources /12.  
Disposition of Comments

## Combined Topic Refinement and Systematic Review

Authorship forms and PRISMA checklist: SRC Secure Site: Resources /ScholarOne (formerly Manuscript Central) /EPC Author Training Materials

### 26. [Post-report activities \(see Chapter B\).](#)

These activities include

- SRDR upload
- Feedback Form
- AHRQ Publication/posting on website
- Assist with Translation and Dissemination

## 3. [Schedule of Deliverables](#)

### Table D. Sample Deliverable Schedule for Combined Topic Refinement and Systematic Review

The Task Order Officer (TOO) reviews deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. For deliverables after the Final Protocol and TEP lists, due dates vary by SR size. The schedule may be shortened if the Key Questions are posted during the pre-award period rather than during topic refinement. Refer to the task order for the timeline. *Italics denote optional items.* **Note: an abbreviated version of this timeline is included in contract documents.**

**NOTE: TA and P2P programs have unique deliverable schedules.** Please refer to the task order for complete details.

### Table D1: Topic Refinement phase

Task	Recipient	Weeks from TR Award Date
Pre-Kickoff Call		
Upload timeline and staffing plan to Secure Site. Notify TOO.	Secure Site, notify TOO	1
Upload Staff Disclosure forms and confidentiality agreements to Secure Site. Notify TOO.	Secure Site, notify TOO	13 days
Upload proposed stakeholder list (Key Informants (KI) and Technical Experts (TEP)) to Secure Site. Notify TOO.	Secure Site, notify TOO	13 days
Kickoff Call		2
Upload summary of call discussion and decisions to Secure Site. Notify TOO. Distribute summary to call participants.	Secure Site, notify TOO	1 week after Kickoff Call
Upload CVs, Disclosure forms and confidentiality agreements for each	Secure Site, notify TOO	Prior to KI or TEP Call

## Combined Topic Refinement and Systematic Review

Task	Recipient	Weeks from TR Award Date
KI and TEP member to the Secure Site. Notify TOO.		
Upload completed TR Document Part One to the Secure Site. Notify TOO.	Secure Site, notify TOO	5
KI Call(s)		8
Upload summary of call discussion and decisions to Secure Site. Notify TOO. Distribute summary to call participants and KIs who could not participate.	Secure Site, notify TOO	1 week after call
Upload completed TR document Parts 2 and 3, and alt text to Secure Site. Notify TOO. The option of the Systematic Review will be submitted to Contracts by the TOO after consultation with the EPC team.	Secure Site, notify TOO	10
<i>KQ Comments Call (optional)</i>		
For TA Program: Revised KQ posting document, disposition of comments table	Secure Site, TA program staff, notify TOO	
Upload Draft Protocol to Secure Site. Notify TOO.	Secure Site, notify TOO	19
SR award		19

**Table D2: Systematic Review Phase with simultaneous peer review and public comment**

Task	Recipient	Weeks from SR Award Date (Small)	Weeks from SR Award Date (Medium)	Weeks from SR Award Date (Large)
For each TE: disclosure form, confidentiality form, and CV. Upload to Secure Site. Notify TOO.	Secure Site, notify TOO			
Upload summary of TEP Call #1 discussion and decisions to Secure Site. Notify TOO. Distribute summary to call participants and TEP members who could not participate.	Secure Site, notify TOO	1 week after TEP Call #1	1 week after TEP Call #1	1 week after TEP Call #1
Upload Final Protocol and alt text to Secure Site. Notify TOO.	Secure Site, notify TOO	5	5	5

## Combined Topic Refinement and Systematic Review

Task	Recipient	Weeks from SR Award Date (Small)	Weeks from SR Award Date (Medium)	Weeks from SR Award Date (Large)
Submit proposed peer review list to TOO for review and approval. Upload to Scholar One after approval.	Secure Site, notify TOO	8	15	19
Preliminary list of included studies and mock-up of summary tables	Secure Site, notify TOO	12	17	19
<i>TEP Call #2 (optional)</i>				
Upload summary of TEP Call discussion and decisions to Secure Site. Notify TOO. Distribute summary to call participants and TEP members who could not participate.	Secure Site, notify TOO	1 week after TEP Call #2	1 week after TEP Call #2	1 week after TEP Call #2
Upload Draft Report, alt text spreadsheet, and PRISMA Checklist to Scholar One. Notify TOO.	Scholar One, notify TOO	20	27	31
Presentation of draft report findings to Partner				
<i>Discuss by conference call peer review or public comments on the Draft Report with the AE and TOO (optional).</i>		31	38	42
Upload Final Report, alt text spreadsheet, PRISMA Checklist, and Disposition of Comments to Scholar One. Notify TOO.	Scholar One, notify TOO and CO	34	41	45
Upload data files to SRDR	SRDR, notify TOO	35	42	46
Complete feedback form	Secure Site, notify TOO	35	42	46
Upload call summary as status report to Secure Site. Notify TOO.	Secure Site, notify TOO	Monthly	Monthly	Monthly



## Combined Topic Refinement and Systematic Review

**Table D3: Systematic Review Phase with Sequential Peer Review and Public Comment**

Task	Recipient	Weeks from SR Award Date (Small)	Weeks from SR Award Date (Medium)	Weeks from SR Award Date (Large)
For each TE: disclosure form, confidentiality form, and CV. Upload to Secure Site. Notify TOO.	Secure Site, notify TOO			
Upload summary of TEP Call #1 discussion and decisions to Secure Site. Notify TOO. Distribute summary to call participants and TEP members who could not participate.	Secure Site, notify TOO	1 week after TEP Call #1	1 week after TEP Call #1	1 week after TEP Call #1
Upload Final Protocol and alt text to Secure Site. Notify TOO.	Secure Site, notify TOO	5	5	5
Submit proposed peer review list to TOO for review and approval. Upload to Scholar One after approval.	Secure Site, notify TOO	8	15	19
Preliminary list of included studies and mock-up of summary tables	Secure Site, notify TOO	12	17	19
<i>TEP Call #2 (optional)</i>				
Upload summary of TEP Call discussion and decisions to Secure Site. Notify TOO. Distribute summary to call participants and TEP members who could not participate.	Secure Site, notify TOO	1 week after TEP Call #2	1 week after TEP Call #2	1 week after TEP Call #2
Upload Draft Report, alt text spreadsheet, and PRISMA Checklist to Scholar One. Notify TOO.	Scholar One, notify TOO	20	27	31
Presentation of draft report findings to Partner				
<i>Discuss by conference call peer review comments on the Draft Report with the AE and TOO (optional).</i>		27	34	38



### ***Combined Topic Refinement and Systematic Review***

<b>Task</b>	<b>Recipient</b>	<b>Weeks from SR Award Date (Small)</b>	<b>Weeks from SR Award Date (Medium)</b>	<b>Weeks from SR Award Date (Large)</b>
Upload peer-reviewed draft report, disposition of comments table, alt text, and PRISMA checklist to Scholar One. Notify TOO	Scholar One, notify TOO and CO	30	37	41
Upload Final Report, alt text spreadsheet, PRISMA Checklist, and Disposition of Comments to Scholar One. Notify TOO.	SRDR, notify TOO	40	47	51
Upload data files to SRDR	Secure Site, notify TOO	41	48	52
Complete feedback form	Secure Site, notify TOO	41	48	52
Upload call summary as status report to Secure Site. Notify TOO.	Secure Site, notify TOO	Monthly	Monthly	Monthly

## ***Combined Topic Refinement and Systematic Review***

The “Resources” section on the SRC Secure Site has pertinent guidance and templates in these folders:

<https://www.epc-src.org/>

- /EPC Process Resources
  - /01. EPC Program Policies and Procedures
  - /02. Publishing Guidelines and Templates
  - /05. Topic Refinement
  - /08. Systematic Review Protocol
  - /09. Technical Expert Panel
  - /10. CER Content Guidance (Report and ES)
  - /12. Disposition of Comments
- /EPC Shared Resources and Samples
  - /SRDR uploading
- /Stakeholder Engagement/KIs
  - /Resources for Researchers
- /Technology Assessment Program
- /ScholarOne (formerly Manuscript Central)
  - EPC Author Training Materials
  - PRISMA Checklist

## E. Standalone Systematic Review (without Topic Refinement)

### Overview of key process steps (same numbering as Combined TR/SR)

(Ctrl + Click to follow links)

1. [Pre-Kickoff Call Activities](#)
2. [Kickoff Call](#)
9. [Draft Protocol](#)
10. [Assemble Technical Expert Panel](#)
11. [1st TEP Call](#)
12. [Final Protocol and Posting](#)
13. [SEADs Portal and optional Federal Register Notice](#)
14. [Literature Review](#)
15. [Optional TEP Calls](#)
16. [Monthly Update Calls](#)
17. [Proposed Peer Reviewer List](#)
18. [Preliminary list of included studies and mockup of summary tables](#)
19. [Draft Report](#)
20. [Peer Review](#)
21. [Presentation of Draft Report to Partner and TEP](#)
22. [Peer-reviewed Draft Report for sequential peer review and public comment](#)
23. [Post Draft Report for Public Comment](#)
24. [Literature Update](#)
25. [Final Report \(Systematic Review\)](#) and [Disposition of Comments](#)
26. [Post report activities](#)

### 1. Overview of Systematic Review without Topic Refinement:

A Systematic Review thoroughly assesses and synthesizes research literature to answer Key Questions that are important to stakeholders. When a standalone Systematic Review is awarded, the decisional dilemmas are identified and the topic scope, Key Questions and PICOTs have already been refined. The first deliverable is the Draft Protocol. The deliverable schedule reflects this difference.

### 2. Standalone SR Process Steps:

1. [Pre-Kickoff Call Activities](#) same as the combined TR/SR
2. [Kickoff Call](#) same as the combined TR/SR

**Steps 3-8 do not apply to a standalone SR**

9. [Draft Protocol](#) same as the combined TR/SR

All other process steps are the same as the combined TR/SR chapter.

### **3. Standalone SR Deliverable Schedule:**

**Table E1. Sample Deliverable Schedule for Systematic Review with Simultaneous Peer Review and Public Comment.**

The Task Order Officer (TOO) will review deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. For deliverables after the Final Protocol and TEP lists, due dates vary by SR size. *Italics denote optional items.* **Note: an abbreviated version of this timeline is included in contract documents.**

<b>Deliverable</b>	<b>Recipient</b>	<b>Weeks from Award (Any Size)</b>
Schedule of deliverables and staffing plan	Secure Site, notify TOO	1
For each EPC staff: COI disclosure, confidentiality agreement and mitigation plan if needed	Secure Site, notify TOO	2
Proposed TEP list	Secure Site, notify TOO	2
Kickoff Call minutes	Secure Site, notify TOO	1 week after call
Draft Protocol	Secure Site, notify TOO	4
For each TE: CV, disclosure COI, confidentiality agreement and rationale if needed	Secure Site, notify TOO	Prior to TEP Call
TEP Call #1 minutes	Secure Site, notify TOO	1 week after call
Final Protocol and alt text spreadsheet	Secure Site, notify TOO	10

## Standalone Systematic Review

<b>Deliverable</b>	<b>Recipient</b>	<b>Weeks from Award (Small SR)</b>	<b>Weeks from Award (Medium SR)</b>	<b>Weeks from Award (Large SR)</b>
Peer Review list	TOO. Upload to ScholarOne after approval	13	20	24
<i>(optional) TEP call #2 summary</i>	Secure Site, notify TOO	<i>One week after Call</i>	<i>One week after Call</i>	<i>One week after Call</i>
Preliminary list of included studies and mock-up of summary tables	Secure Site, notify TOO	17	22	24
Draft Report, alt text spreadsheet and PRISMA checklist	Scholar One. Notify TOO	25	32	36
Presentation of draft report to Partner and TEP				
Final Report, alt text spreadsheet, PRISMA checklist, author response, and final disposition of comments table	Scholar One, Notify TOO and CO	39	46	50
Data files	SRDR	40	47	51
Feedback form	Secure Site	40	47	51
Monthly Call summary	Secure Site, Notify TOO	Monthly	Monthly	Monthly

**Table E2. Sample Deliverable Schedule for Systematic Review with Sequential Peer Review and Public Comment.**

The Task Order Officer (TOO) will review deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. For deliverables after the Final Protocol and TEP lists, due dates vary by SR size. *Italics denote optional items.* **Note: an abbreviated version of this timeline is included in contract documents.**

Deliverable	Recipient	Weeks from Award (Any Size)
Schedule of deliverables and staffing plan	Secure Site, notify TOO	1
For each EPC staff: COI disclosure, confidentiality agreement and mitigation plan if needed	Secure Site, notify TOO	2
Proposed TEP list	Secure Site, notify TOO	2
Kickoff Call minutes	Secure Site, notify TOO	1 week after call
Draft Protocol	Secure Site, notify TOO	4
For each TE: CV, disclosure COI, confidentiality agreement and rationale if needed	Secure Site, notify TOO	Prior to TEP Call
TEP Call #1 minutes	Secure Site, notify TOO	1 week after call
Final Protocol and alt text spreadsheet	Secure Site, notify TOO	10

## Standalone Systematic Review

<b>Deliverable</b>	<b>Recipient</b>	<b>Weeks from Award (Small SR)</b>	<b>Weeks from Award (Medium SR)</b>	<b>Weeks from Award (Large SR)</b>
Peer Review list	TOO. Upload to ScholarOne after approval	13	20	24
<i>(Optional) TEP call #2 summary</i>	<i>TOO</i>	<i>One week after Call</i>	<i>One week after Call</i>	<i>One week after Call</i>
Preliminary list of included studies and mock-up of summary tables	TOO	17	22	24
Draft Report, alt text spreadsheet and PRISMA checklist	Scholar One, Notify TOO	25	32	36
Presentation of draft report to Partner and TEP				
Upload peer-reviewed draft report, disposition of comments table, alt text, and PRISMA checklist to Scholar One.	Scholar One Notify TOO	35	42	46
Final Report, alt text spreadsheet, PRISMA checklist, author response, and final disposition of comments table	Scholar One, Notify TOO and CO	45	52	56
Data files	SRDR	46	53	57
Feedback form	Secure Site	46	53	57
Monthly Call summary	Secure Site, Notify TOO	Monthly	Monthly	Monthly

### F. Surveillance

#### Overview of key process steps

1. [Pre-kickoff call activities](#)
2. [Kickoff Call](#)
3. [Assemble Content Experts](#)
4. [Literature Scan](#)
5. [Findings Matrix](#)
6. [Content Expert Input](#)
7. [Surveillance Document](#)
8. [Monthly Update Calls](#)
9. [Post-report activities](#)

#### 1. [Overview of Surveillance](#)

The purpose of surveillance is to assess whether a systematic review funded by AHRQ needs an update. Generally, the process begins about 3 years after a review is published. We perform an abbreviated literature search and enlist content experts to help us to judge whether the review's findings are current. If the majority of the findings are unchanged, we endorse the prior review. If the findings are no longer current, AHRQ will archive the review.

#### 2. [Surveillance Process Steps](#)

1. [Pre-kick-off call activities](#) same as combined TR/SR, except:

KI and TEP lists are not required

2. [Kickoff Call](#)

The EPC will convene a conference call with the TOO. Upon award, the TOO will inform the EPC of optional participants, including other AHRQ staff or individuals involved in the project. The purpose of the Kickoff Call is to:

- Discuss purpose of requested project.
- Review elements of work to be performed.
- Describe a plan for developing surveillance report.
- Establish lines of communication between the EPC, TOO, stakeholders, other AHRQ staff, and partners.
- Discuss proposed content experts

3. [Assemble Content Experts](#)

The EPC will use the original SR to identify potential content experts. These can be chosen from the original EPC lead author/content expert, TEP members and Peer Reviewers. Since we would like at least two completed expert reviews, we recommend inviting at least eight reviewers



## Surveillance

Recruitment: After the Kickoff Call, the EPC must recruit content experts and obtain signed COI Disclosure forms. The EPC should advise the content experts that, unless they opt out, they the final surveillance report will acknowledge them by name.

Manage Conflict of Interest (COI) Disclosure: The PI should review the COI Disclosure forms for potential financial or non-financial conflicts of interest. If a COI is identified, the PI must submit a rationale for including this individual to the TOO for discussion with the EPC Program director.

Approval: The TOO should acknowledge acceptance of the COI Disclosure forms (and rationale) within 1 week. Content experts may not serve until they have been approved by the TOO.

The EPC will develop a draft invitation email for content experts, upload it to the SRC Secure Site, and notify the TOO.

**Resource:** SRC Secure Site: Resources /Surveillance Reports /Surveillance Process, guidance, templates 2018. TEP email-surveillance.

### 4. Literature Scan

The EPC will search the published literature, starting at least six months prior to the last search date of the original systematic review, up to present. Simplified strategies are acceptable, given that this is not a comprehensive literature review, but a scan to detect signals that a review might not be current. Formal data abstraction and synthesis are not required. If the original review lists drugs/devices, search the FDA website for boxed warnings or Drug Safety Labeling Changes.

**Resource:** SRC Secure Site: Resources /Surveillance Reports /Surveillance Process, guidance, templates 2018. Surveillance Process-EPC

### 5. Develop Findings Matrix

A “Findings Matrix” is a table with original findings/conclusion from the original Systematic Review and the results of the targeted literature search. Upload the completed Findings Matrix to the SRC Secure Site, and notify the TOO.

**Resource:** SRC Secure Site: Resources /Surveillance Reports /Surveillance Process, guidance, templates 2018. Surveillance Matrix Template.

### 6. Get content expert input on the findings matrix

The EPC sends the completed Findings Matrix to each content expert after the TOO approves the expert and the matrix. We ask the content experts to respond within 2 weeks with their opinion about the currency of **each finding** in the systematic review. Deadlines may be extended to ensure input from at least two content experts.

### 7. Submit Surveillance Report

## Surveillance

The EPC will prepare the narrative Surveillance Report, using the template provided, with expert response summarized in table format along with the EPC assessment of currency. The narrative provides justification for the EPC's global assessment of the accuracy of the complete SR. The EPC must upload the completed Surveillance Report to the SRC Secure Site, and notify the TOO.

**Resource:** SRC Secure Site: Resources /Surveillance Reports /Surveillance Process, guidance, templates 2018. Surveillance report Template.

8. [Monthly Update Calls](#)- Same as Step 16, Combined TR/SR

9. [Post-report activities. See Chapter B.](#)

### 3. [Schedule of deliverables](#)

**Table F. Sample Surveillance Deliverable Schedule.**

The Task Order Officer (TOO) reviews deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. *Italics denote optional items.* **Note: an abbreviated version of this timeline is included in contract documents.**

Task	Recipient	Weeks from Award
Deliverable schedule and staffing plan	Secure Site. Notify TOO.	1
For each EPC Staff: COI form, confidentiality form	Secure Site. Notify TOO.	2
Proposed content expert list	Secure Site. Notify TOO.	2
Draft invitation email for content experts		
Kickoff Call summary	Secure Site. Notify TOO.	1 week after Kickoff Call
Distribute summary to call participants.		
Draft Findings Matrix	Secure Site. Notify TOO.	8
For each content expert: COI form	Secure Site. Notify TOO.	(Prior to distributing Findings Matrix)

## ***Surveillance***

<b>Task</b>	<b>Recipient</b>	<b>Weeks from Award</b>
Surveillance Report	Secure Site. Notify TOO.	14
Feedback form	Secure Site	15
Monthly Call Summary	Secure Site. Notify TOO.	Monthly

## G. Systematic Review Update

### Overview of key process steps (same numbering as Combined TR/SR)

1. [Pre-Kickoff Call Activities](#)
2. [Kickoff Call](#)
9. [Draft Protocol](#)
10. [Assemble Technical Expert Panel](#)
11. [1st TEP Call](#)
12. [Final Protocol and Posting](#)
13. [SEADS and Federal Register Notice](#)
14. [Literature Review](#)
15. [Optional TEP Calls](#)
16. [Monthly Update Calls](#)
17. [Proposed Peer Reviewer List](#)
18. [Preliminary list of included studies and mock-up of summary tables](#)
19. [Draft Report](#)
20. [Peer Review](#)
21. [Draft Report Presentation](#)
22. [Peer-reviewed Draft Report for sequential peer review and public comment](#)
23. [Post Draft Report for Public Comment](#)
24. [Literature Update](#)
25. [Final Report \(Systematic Review\) and Disposition of Comments](#)
26. [Post-report activities](#)

### **1. Overview of Systematic Review Update**

For a SR Update, the TEP will provide input on which areas of the previous AHRQ SR's scope (including any Key Questions and/or inclusion criteria) require revision, and on the size of the update needed. They may also identify new studies, interventions or methods relevant to the SR topic.

### **2. Process Steps:**

1. **Pre-Kickoff Call Activities-** See Chapter A
2. **Kickoff Call-** Same as Combined TR/SR
9. **Draft Protocol -** Same as Combined TR/SR, except:

## *Systematic Review Update*

- The EPC must start with the previous SR's Final Protocol, and revise as necessary. The Protocol must include a rationale for the update, the presence or absence of changes to the Key Questions and PICOTS. It must indicate that the report is an update and provide a reference to the previous SR.

### **Steps 10-18 are the same as Combined TR/SR**

#### **19. Draft Report-** Same as Combined TR/SR, except:

- The EPC must prepare the draft Systematic Review (Draft Report) and appendices that includes a summary of the updated evidence in addition to what it adds to the previous review. Add a summary section prior to the Evidence Summary, to cover major changes since the previous SR, particularly any changes to the methods and/or the key findings. Reference the previous report in the background, conclusions, and research gaps sections.

### **Steps 20-26 are the same as Combined TR/SR**

3. **Schedule of Deliverables for Systematic Review Update.** Same as Standalone SR

### **H. Rapid Review**

#### **Overview of key process steps**

1. [Pre kick-off call activities](#)
2. [Kick-off call](#)
3. [Brief Protocol](#)
4. [Literature review and analysis](#)
5. [Proposed peer reviewer list if peer review planned](#)
6. [Draft report if peer review planned](#)
7. [Peer review optional](#)
8. [Final report](#)
9. [Final Report Presentation with partner optional](#)
10. [Public comment optional](#)
11. [Post-report activities](#)

#### **1. Overview of the Rapid Review**

An EPC methods paper (<https://effectivehealthcare.ahrq.gov/topics/rapid-review-production/white-paper>) describes four different types of Rapid Evidence Products: rapid response, rapid review, evidence inventory, and automated approaches. Of the different types of evidence products, we provide here an overview for the rapid review. The rapid review is intended to provide an assessment of evidence in a compressed timeframe to inform an end-user's decision. While the steps are similar to those of a "typical" systematic review, the methods may be different. The intent of a Rapid Review is to develop a product that balances quality, rigor, and replicability with utility, transparency, and timeliness.

An EPC program-wide work group emphasized the need for flexibility in the methods used based on the end-users' needs and the evidence identified. Examples of variability include restrictions on the scope, limits for the literature searches, processes for data abstraction, and decisions about risk of bias assessment and strength of evidence grading.

A Federal agency may request a rapid review through an IAA to inform their own decisions. For these projects, the Sponsoring Partner provides the topics and rapid review requirements. These requirements may be related to items such as the scope of the literature search and need for risk of bias assessments.

#### **2. Rapid Review Process**

**1. Pre-kickoff activities.** See [Chapter A](#).

##### **2. Kick-off call**

The EPC must lead a conference call with the TOO and Partner, in order to:

- Introduce and discuss roles of the Partner
- Review purpose of the product, key decisional dilemmas and the elements of work to be performed, such as any presentations or webinars.

## **Rapid Evidence Products**

- Discuss key questions and PICOTS in light of the key decisional dilemmas
- Discuss the proposed methods for the rapid review including
  - Risk of bias assessment
  - Strength of evidence grading
  - Limitations of the search
- Discuss whether optional items are needed
  - Peer review
  - Public comment
  - Webinar with partner summarizing findings from the final report
- Review role of Associate Editor:
  - AE peer review of Draft Report
  - Optional AE review of Final Report
- Establish lines of communication between the EPC, TOO, and Partner.

### **3. Brief Protocol**

The EPC will develop a brief protocol about the project, similar to the length of an abstract. At minimum, it will include the following elements:

- 2-3 sentence background
- Purpose of review
- High-level overview of methods, focusing on key steps that will be streamlined for the rapid review

The EPC will submit this to the TOO, who will review and route for EPC Program leadership review and posting on the EHC website.

#### **Resources:**

Overview and Guidance Document on the Secure Site at [Resources /EPC Process Resources /15. Rapid Evidence Products](#)

### **4. Literature search and analysis**

The EPC must systematically search, abstract, review, and analyze the scientific evidence for each Key Question. Consistent with the aim of a rapid evidence product, these steps may be streamlined. See resources for specific guidance about considerations around the literature search; screening and study selection; data extraction; risk of bias assessment; strength of evidence grading; and synthesis.

#### **Resources:**

Overview and Guidance Document on the Secure Site at [Resources /EPC Process Resources /15. Rapid Evidence Products](#)

### **5. Proposed peer reviewer list, if Peer Review is planned**

This is the same as TR/SR, except:

- The Peer Review list should include two to four first choice peer reviewers , and two to four alternate peer reviewers (invited only if first choice reviewers decline)
- The goal is three independent and unbiased peer reviewers who *agree* to participate

## ***Rapid Evidence Products***

### **6. Draft report if Peer Review is planned**

This is the same as TR/SR except:

- Review and approval will be similar to the process used for sequential Peer Review and public comment.

### **7. Peer Review-optional**

Planned Peer Review is the same as TR/SR with the following exceptions:

- Peer Review will be for 2 weeks
- The goal is to have one or two submitted Peer Reviews by the close of the Peer Review period.
- The AE and TOO review will be similar to the process for sequential Peer Review and public comment.
- Public comment is optional

During the Peer Review period, the EPC should identify potential journals for publication submission, and begin to develop a journal article.

### **8. Final Report**

This step is similar to TR/SR with the following changes:

- Because of the short timeframe of the rapid review, an updated literature search is not required.
- The Disposition of Comments document will provide a high-level summary of comments and their response. This document will not be posted on the EHC website.

### **9. Final Report Presentation with Partner-Optional**

If a webinar or teleconference with the Partner is undertaken, the EPC will convene a webinar or teleconference with the TOO and Partner representatives to present a summary of findings from the evidence report.

### **10. Optional public comment and disposition of comments**

This is the same as TR/SR with the following changes

- An optional public comment period would last 2 weeks
- Based on the content of comments from the public and/or Partner the EPC may revise the report.
- A formal disposition of comments is not required, however a high-level summary and the EPC response should be submitted with the revised report.

### **11. Post-report activities. See Chapter B.**



## Rapid Evidence Products

### 3. Schedule of Deliverables

**Table H. Sample Rapid Review Deliverable Schedule**

The Task Order Officer (TOO) reviews deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. *Italics denote optional items.* **Note: an abbreviated version of this timeline is included in contract documents.**

Task/Deliverable	Recipient	Weeks from award
Staffing plan, project management file/schedule of deliverables, COI disclosure forms, confidentiality forms, mitigation plan if needed	Secure Site. Notify TOO.	1
Kickoff call		2
Summary of Kickoff Call	Secure Site. Notify TOO.	3
Submit abstract for posting on EHC website to TOO	Secure Site. Notify TOO.	6
Proposed peer reviewer list if peer review is planned	Secure Site. Notify TOO.	1-2 months before draft report
Submit Draft report	Scholar One, Notify TOO	18
<i>Peer review optional</i>		20
Submit final report	Scholar One, Notify TOO	24
<i>Optional final report presentation with Partner</i>		
<i>Optional public comment period</i>		26
<i>Submit revised final report if needed</i>		30
Upload to SRDR and complete feedback form	SRDR, Secure Site. Notify TOO.	31

The “Resources” section on the SRC Secure Site has pertinent guidance and templates in these folders:

<https://www.epc-src.org/>

■ /EPC Process Resources

- /01. EPC Program Policies and Procedures
- /02. Publishing Guidelines and Templates
- /10. CER Content Guidance (Report and ES)
- /15. Rapid Evidence Products

■ /EPC Shared Resources and Samples

- /SRDR uploading

■ /ScholarOne (formerly Manuscript Central)

- EPC Author Training Materials
- PRISMA Checklist

### **I. Rapid Response**

#### **1. Overview of the Rapid Response**

An EPC methods report by Hartling et al (<https://effectivehealthcare.ahrq.gov/topics/rapid-review-production/white-paper>) outlined four type of rapid evidence products: rapid response, rapid review, evidence inventory, and automated approaches. Topics are considered for a rapid evidence product based on factors related to the type of questions, timing, and type of decision. The Rapid Response is similar to a Topic Development Brief, except that the final report provides an answer based on the best available evidence. The “inventory” is similar to the Technical Brief, described later in this guide.

#### **2. Rapid Response Process Steps**

Methods for the rapid response are in development. At minimum it includes

1. Pre-kickoff call activities. See [Chapter A](#).
2. [Kickoff Call](#)
3. [Literature Scan](#)
4. [Final report](#). Same as TR/SR.
5. Post-report activities. See [Chapter B](#).

#### **3. Schedule of Deliverables**

The timeline for this product has not been established.

### J. Technical Briefs

#### Overview of key process steps (same numbering as Combined TR/SR)

1. [Pre-Kickoff Call Activities](#)
2. [Kickoff Call](#)
3. [Assemble Key Informant Panel](#)
12. [Protocol](#)
  - a. [Literature scan](#)
  - b. [KI interviews](#)
13. [SEADs Portal and Optional Federal Register Notice](#)
16. [Monthly Update Calls](#)
17. [Proposed Peer Reviewer List](#)
19. [Draft Report](#)
20. [Peer Review](#)
21. [Draft Report Presentation](#)
22. [Peer-Reviewed Draft Report](#)
23. [Posting for Public Comment](#)
24. [Literature Update](#)
25. [Final Report](#) and [Disposition of Comments](#)
26. [Post-report activities](#)

#### 1. Overview of Technical Briefs:

A **Technical Brief** (TB) is a rapid evidence product on an emerging medical technology or intervention with limited available evidence, or one with some evidence but no common framework for evaluating the evidence. Like an evidence inventory, the Technical Brief provides an overview of key issues related to the intervention such as current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. A Technical Brief does not grade evidence or synthesize data on outcomes, and does not attempt to determine whether an intervention is safe or effective. The goals of a Technical Brief are to provide an early objective description of the current science, a potential framework for assessing the intervention, and to identify future research needs.

Technical Briefs do not undergo Topic Refinement.

**Resource:** SRC Secure Site: Resources /EPC Process Resources /11. Technical Brief and TB Protocol Guidance.

## **Technical Briefs**

### **2. Technical Brief Process Steps:**

- 1. Pre-kickoff Call activities (See Chapter A)**
- 2. Kickoff Call.** Same as Combined TR/SR
- 3. Assemble the Key Informant (KI) panel.** Same as Combined TR/SR.

**Steps 4-11 do not apply to Technical Briefs**

#### **12. Final Protocol and Posting**

Search and review the literature to evaluate the appropriateness and scope of a Technical Brief on the chosen topic area. This preliminary literature review is not meant to be a synthesis of all available information but to inform the scope of the topic. Local subject experts may be consulted informally for orientation to the subject.

Based on this brief literature review and discussions with local experts, the EPC will develop the Technical Brief Protocol.

**Resource:** Content guidance SRC Secure Site: Resources /EPC Process Resources /11. Technical Brief and TB Protocol Guidance.

The EPC will submit the TB protocol to the TOO for review. The TOO will follow the usual process for review and approval and will notify the Partner when the Protocol is posted.

##### **a. Research Phase: Systematic Literature Scan**

Based on its approved Protocol, the EPC shall conduct a systematic and comprehensive search of the published and unpublished literature to address each question.

Since this is a literature scan rather than a full literature review, abstraction and synthesis of data from trials, depending on the topic, may be limited to descriptive study variables identified in the Protocol. However, the EPC should read the full text articles (not just the abstracts).

##### **b. Research Phase: Key Informant (KI) Interviews**

The EPC will hold calls with individual KIs or with a group of KIs. In general, it is advisable to plan the calls as an iterative process, starting shortly after the literature scan, so that early interviews may identify additional informants (within the limits of the timeline). The focus should be on finding and balancing the relevant perspectives rather than on recruiting purely unbiased informants. Use KI input to help identify important questions that can be explored using evidence from other sources. The interviews should not be treated as survey data. For some points, KIs may be the only source for information about context or controversy. In these cases, the report should note both the KI opinion and the lack of corroborating literature.

#### **13. SEAD portal and Federal Register Notice-** Same as Combined TR/SR

## **Technical Briefs**

**14. Literature Review-** Does not apply to Technical Briefs

**15. Optional TEP Calls-** Does not apply to Technical Briefs

**16. Monthly Update Calls-** Same as Combined TR/SR

**17. Proposed Peer Reviewer List-** Same as Combined TR/SR, except:

- SRC will ask the EPC to upload the list 2 months before the draft report is due.
- List includes Key Informants instead of Technical Experts.

**19. Draft Report** Same as Combined TR/SR

**Resource:** Content guidance is found at: SRC Secure Site: Resources /EPC Process Resources /11. Technical Brief and TB Protocol Guidance. The required format (template) is found at: SRC: Resources /EPC Process Resources /02. Publishing Guidelines and Templates.

**Steps 20-26 are the same as Combined TR/SR**

## Technical Briefs

### 3. Schedule of Deliverables

The Task Order Officer (TOO) will review deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. *Italics denote optional items.* **Note: an abbreviated version of this timeline is included in contract documents.**

**Table J1. Sample Deliverable Schedule for Technical Brief with Simultaneous Peer Review and Public Comment.**

Task	Recipient	Weeks from Award
Deliverable schedule, staffing plan	Secure Site. Notify TOO.	1
For each EPC Staff: staff COI forms and confidentiality agreements	Secure Site. Notify TOO.	2
Proposed Key Informant list	Secure Site. Notify TOO.	2
Kickoff Call summary, and distribute summary to call participants	Secure Site. Notify TOO.	1 week after Kickoff Call
Protocol, alt text spreadsheet	Secure Site. Notify TOO.	4
Proposed peer review list	TOO, Scholar One after approval.	7
For each KI: COI form and confidentiality agreement	Secure Site. Notify TOO.	Prior to KI Call
KI call summaries, Distribute summaries to call participants.	Secure Site. Notify TOO.	1 week after call
Draft Report, Alt text spreadsheet	Scholar One. Notify TOO.	15
Presentation of draft report to Partner and/or TEP		
Final Report, Alt text spreadsheet, Disposition of Comments Table	Scholar One. Notify TOO and CO	29
Data files	SRDR	30
Feedback form	Secure Site	30
Monthly Call Summary	Secure Site. Notify TOO.	Monthly

## Technical Briefs

**Table J2. Sample Deliverable Schedule for Technical Brief with Sequential Peer Review and Public Comment**

Task	Recipient	Weeks from Award
Deliverable schedule, staffing plan	Secure Site. Notify TOO.	1
For each EPC Staff: staff COI forms and confidentiality agreements	Secure Site. Notify TOO.	2
Proposed Key Informant list	Secure Site. Notify TOO.	2
Kickoff Call summary, and distribute summary to call participants	Secure Site. Notify TOO.	1 week after Kickoff Call
Protocol, alt text spreadsheet	Secure Site. Notify TOO.	4
Proposed peer review list	TOO, Scholar One after approval.	7
For each KI: COI form and confidentiality agreement	Secure Site. Notify TOO.	Prior to KI Call
KI call summaries, Distribute summaries to call participants.	Secure Site. Notify TOO.	1 week after call
Draft Report, Alt text spreadsheet	Scholar One. Notify TOO.	15
Presentation of draft report to Partner and/or TEP		
Peer-reviewed Draft Report	Scholar One. Notify TOO	25
Final Report, Alt text spreadsheet, Disposition of Comments Table	Scholar One. Notify TOO and CO	35
Data files	SRDR	36
Feedback form	Secure Site	36
Monthly Call Summary	Secure Site. Notify TOO.	Monthly

### **Overview of typical key process steps**

*(Ctrl + Click to follow links)*

1. [Pre-Kickoff Call Activities](#)
2. [Kickoff Call](#)
3. [Abstract for Posting](#)
4. [Draft Protocol](#)
5. [Assemble Technical Expert Panel](#)
6. [TEP Call](#)
7. [Final Protocol and Posting](#)
8. [Proposed Peer Reviewer List](#)
9. [Monthly Update Calls](#)
10. [Draft Report](#)
11. [EPC Program Input](#) (methods guidance papers only)
12. [Post Draft Report for Public Comment](#)
13. [Peer Review](#)
14. [Final Report](#) and [Disposition of Comments](#)
15. [Post-report activities](#)

## **K. EPC Methods and Methods Guidance Reports**

### **1. Overview of Methods Reports:**

#### **Overview:**

This section provides guidance about processes for methods reports, methods guidance reports, and white papers. These reports are diverse and processes may vary, but here we outline the typical steps of a methods project. When steps are the same as Systematic Review, we refer users to that section of Chapter C.

**Resources:** See the “Publishing Guidelines for Reports” for details on specific methods reports. SRC Secure Site: Resources/EPC Process Resources 02. Publishing Guidelines and Templates. Publishing Guidelines for Reports

### **2. Methods Reports Process Steps:**

#### **1. Pre-kick-off Call Activities** (See [Chapter A](#))

For methods guidance papers, the TOO may be a workgroup member.

#### **2. Kickoff Call:** Same as Combined TR/SR.

#### **3. Abstract for Posting**

Provide a brief summary in non-technical language that describes the key components of the proposed study for public disclosure about the project. The abstract should include a



Background, Objectives, and Approach.

The EPC will submit the Abstract to the TOO, who will review for accuracy and consistency with guidance, and route for posting on the EHC website.

**Resource:** SRC: Resources /EPC Process Resources /02. Publishing Guidelines and Templates

#### **4. Draft Protocol**

The EPC will develop the Draft Protocol (including the following elements: key contact information, a brief background of the topic, any contextual issues, preliminary framework, methodology, timeline, and other relevant information as requested by the TOO). The EPC should adapt the Protocol Content Guidance for their project.

**Resources** for template and guidance: SRC Secure Site: Resources /EPC Process Resources /08. Systematic Review Protocol.

Otherwise, the Draft Protocol is managed the same as Combined TR/SR

#### **5. Assemble TEP *(if a TEP is convened)* Same as Combined TR/SR**

#### **6. TEP Call *(if a TEP is convened)* Same as Combined TR/SR**

#### **7. Final Protocol. Same as Combined TR/SR, except:**

- If a TEP is not convened, the Draft Protocol becomes the Final Protocol when it is approved by the TOO
- Protocol will not be posted on the EHC website.

#### **8. Proposed Peer Reviewer List Same as Combined TR/SR**

#### **9. Monthly Conference Calls and Summaries. Same as Combined TR/SR**

#### **10. Draft Report**

The EPC will prepare the Draft Methods Report and relevant appendices in manuscript form adapted from the EPC Report template. The final format of the report must be approved by the TOO before submission. The report must be concise and with sufficient detail and clarity to be the primary document. The report must include a structured abstract, background section, description of methods, updated taxonomy if appropriate, and organizational framework.

#### **11. EPC Program Input (Methods Guidance Papers only)**

Draft methods guidance papers must be presented to the all current EPC directors for feedback prior to Peer Review. This may be accomplished via direct email, a posting on the Learning Network and notification of the EPC Directors of the comment period, presentation at an EPC Directors meeting, or through ScholarOne.

**12. Post Draft Report for Public Comment.** Same as Combined TR/SR, except:

- Public comment is optional for White papers

**13. Peer Review of Draft Report.** Same as Combined TR/SR, except:

- White papers are not peer reviewed

**Resource:** Secure Site at: Resources /EPC Process Resources /01. EPC Program Policies and Procedures/ EPC Posting and Review Guide.

**14. Final Report and Disposition of Comments.** Same as Combined TR/SR, except:

- The PRISMA checklist is not required.
- The SRC will send the disposition of peer and public comments table to peer reviewers when the Final Report is accepted.
- The Disposition of comments table will NOT be posted on the Effective Health Care website

**15. Post-report activities.** See Chapter B.

### **3. Methods Reports Deliverable schedule:**

**Table K. Sample Methods Report Deliverable Schedule.** (Example award date is 1/1/2018.) The Task Order Officer (TOO) will review deliverables before final acceptance. Adhere to the due dates indicated to assure payment. Due dates that fall on a weekend or holiday are due on the next business day. *Italics denote optional items.* Note: an abbreviated version of this timeline is included in contract documents

Task	Recipient	Weeks from Award
Schedule of deliverables Staffing plan	Secure Site. Notify TOO.	1
For each EPC staff: Disclosure of COI form Confidentiality agreements	Secure Site. Notify TOO.	1
Kickoff Call summary	Secure Site. Notify TOO.	2
Abstract	Secure Site. Notify TOO.	3
Draft Protocol (Becomes Final Protocol if no TEP)	Secure Site. Notify TOO.	4
<i>Proposed TEP list</i>	Secure Site. Notify TOO.	<i>4</i>
<i>For Each TE:</i> <i>Disclosure of COI forms</i> <i>CV</i> <i>Confidentiality agreement</i>	Secure Site. Notify TOO.	<i>prior to TEP Call</i>

<b>Task</b>	<b>Recipient</b>	<b>Weeks from Award</b>
<i>TEP Call summary To TEP members after approval</i>	Secure Site. Notify TOO.	<i>1 week after TEP Call</i>
<i>Final Protocol</i>	Secure Site. Notify TOO.	<i>2 weeks after TEP Call</i>
Peer Reviewer List	ScholarOne Notify TOO	26
Draft Report Alt Text	ScholarOne Notify TOO	39
Draft Disposition of Comments	Scholar One Notify TOO	44
Final Report Alt text spreadsheet Disposition of Comments	ScholarOne Notify TOO	48
Monthly Call Summaries	Secure Site. Notify TOO.	monthly