



TASKS	Time
<b>1.0 AMPA identifies Initial Writing Team (IWT) and with PM develops initial charter<sup>1</sup></b>	<b>15 days</b>
1.1 SAG, CMER, or Cooperators inform AMPA a TWIG is needed (generally based on perceived capacity in concert with CMER work plan).	1
1.2 AMPA notifies SAGs, CMER, and Policy by email of need for qualified persons to be on IWT. Names of potential participants to be sent to AMPA within 7 working days. Cooperators asked if they want to be added to a contact list for periodic project updates. PM develops email list of interested cooperators to keep informed during project life.	7
1.3 AMPA identifies an Initial Writing Team (2 to 4 persons) (notifies CMER, SAG, Policy); after confirming availability and interest. <sup>2</sup>	7
1.4 AMPA and PM begin to fill in the charter template. The key additions at this step are: 1) the names of the IWT members, 2) a description of the project's basic purpose and any initially known critical questions (based on information from the CMER work plan), and 3) clarification that the first work task will be to establish qualifications needed in a TWIG to recommend potential TWIG members.	
<b>2.0 Initial Writing Team lists needed qualifications, and makes recommendations for TWIG members</b>	<b>31 days</b>
2.1 IWT develops a list of qualifications for the TWIG (to develop study design) and, with AMPA and PM, recommend people to be on the TWIG.	2
2.2 List of qualifications and potential names sent to CMER and SAGs for informal 7 day review; request names of other qualifying persons.	7
2.3 The IWT considers feedback from CMER and amends the list of prospective TWIG members.	1
2.4 AMPA checks the interest and availability of prospective TWIG members to participate through the study design phase. Based on responses and the qualifications list, AMPA develops a draft recommendation for the TWIG team.	7
2.5 CMER to approve the final list of qualifications and the prospective TWIG team. <sup>3</sup>	7
2.6 AMPA formally notifies TWIG members of their selection. The work of the IWT is complete <sup>4</sup> .	4
<b>3.0 TWIG selected and develops testable problem statement and critical questions to guide study design work (beginning of technical work)</b>	<b>19 days</b>
3.1 TWIG develops Objectives, Problem Statement and refines Critical Research Questions to guide Best Available Science (BAS) review and the selection of study design alternatives.	2
3.2 Study objectives, problem statement, and critical research questions provided by email to CMER and SAGs for informal 7 day review.	7
3.3 TWIG revises the objectives, problem statement, and critical research questions as needed based on CMER review.	1
3.4 Policy approves study objectives, problem statement, and critical research questions - to clarify/ prioritize policy questions/needs. <sup>5</sup>	7
<b>4.0 TWIG conducts BAS review and develops study design alternatives</b>	<b>102 days</b>
4.1 TWIG develops document describing BAS addressing the study objectives, problem statement and critical research questions	45
4.1.1 TWIG determines if BAS is adequate to satisfy study objectives and critical questions;	2
4.1.1.1 If so, CMER must concur that no further study is needed. <sup>6</sup> If CMER concurs, documentation and 6 questions then sent to Policy.	14
4.2 TWIG uses BAS to establish study design alternatives and recommendation - includes estimated budgets and time required.	7
4.3 CMER reviews and approves BAS review document and assessment/description of study design alternatives. <sup>7</sup>	14
4.4 Policy reviews alternatives and approves a study design alternative.	7
4.5 TWIG determines if gaps in design team (TWIG) skills exist, and works with AMPA to add new members prior to writing study design.	7
4.5.1 CMER and SAGs provided 7 days to review and approve any changes to TWIG membership or listed TWIG qualifications.	7
<b>5.0 TWIG or Outside Contractor Develops study design</b>	<b>205 days</b>
5.1 TWIG drafts study design.	30
5.1.1 CMER approves study design to go to ISPR.	21
5.2 ISPR review of proposed study design and receipt of comments.	120
5.2.1 Revise study design and prepare response matrix and resubmit to ISPR associate editor.	7
5.3 ISPR concurrence on response matrix and revised study design (non-concurrence issues brought to CMER).	21
5.4 AMPA determines if revised study design is ready for implementation.	3

<sup>1</sup> At the conclusion of each of the 5 steps, the PM will update the charter with new agreements and deliverables.

<sup>2</sup> Before CMER would authorize the IWT, not the AMPA.

<sup>3</sup> Before the approval came at the IWT stage and included CQs, the problem statement, and qualifications and recommended TWIG membership.

<sup>4</sup> Before there was no clear transition from the IWT to the TWIG. This highlights where the team members may be changing in the process.

<sup>5</sup> Before the policy review occurred early in the charter process, but here we wait until the research questions have been potentially develop more thoroughly.

<sup>6</sup> Before there was no CMER review of this critical science decision.

<sup>7</sup> Before no CMER review of alternatives, and their basis.

*6.0 Update Charter and Prepare implementation plan and budget (60 days).*

*60 days*

## Existing Pilot TWIG Process

### Forming a TWIG

Steps:

- 1) **Identify a new project and create an initial writing team to develop the project charter.**
  - CMER, or a SAG working through CMER, will identify a project and authorize an initial writing team (2 to 4 persons) to start drafting a project charter.
  - The purpose of the initial writing team is to develop the draft charter. Members of the initial writing team may or may not end up being on the TWIG that develops the final charter or the study design.
  - The initial writing team will include at least one member of CMER or CMER science staff, and a PM identified by the AMPA as having time to oversee a new project.
- 2) **Develop a draft charter.** The initial writing team approved by CMER will develop a draft project charter that will include:
  - Project title,
  - Problem statement,
  - Critical questions,
  - Purpose statement, and
  - Interim qualifications (knowledge, skills, experience) needed in a TWIG.
    - The CMER staff assigned to the writing team is to put particular emphasis into reviewing the draft project charter from above and any other relevant documents, and using that information to assist in developing a list of draft skills and qualifications needed for TWIG members.
- 3) **CMER Review and Approval.** CMER will review and approve the draft charter and the prospective TWIG candidate list (as well as providing suggestions for additional candidates if needed). Approval or disapproval must be based on the merits of the contents of the charter and not used to limit the options available to the TWIG for designing the study.
- 4) **Charter will be revised as necessary to reflect the identified needs of Policy.** The initial writing group is responsible for revising the charter as needed to meet the research needs of Policy.
- 5) **Final TWIG Membership Identified based on Qualifications and Availability.** AMPA will prioritize the candidates based on CMER input and contact them regarding their ability (interest, availability, and a commitment from their agency/organization) to formally commit to serving on the TWIG.
- 6) **TWIG will finalize the Charter if Needed.** The final TWIG may include members of technical qualifications not possessed by the members of the initial writing team. This final TWIG will be provided a chance to review and suggest critical amendments to the Charter that will help ensure it

results in a successful study. Revisions to the charter must be approved by CMER if s the AMPA determines they substantially deviate from what CMER had previously agreed on.

- 7) **TWIG proceeds to develop study design under revised charter.**