



**Analgesic, Anesthetic, and Addiction Clinical Trial
Translations, Innovations, Opportunities, and Networks
(ACTTION)
Public-Private Partnership with the United States Food and
Drug Administration**

GOVERNANCE and BY-LAWS

Reviewed and approved by the ACTTION Executive Committee

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1. INTRODUCTION

Millions of Americans experience acute and chronic pain. Pain often remains refractory to existing treatments, causing substantial personal distress and considerable societal costs. Despite the scientific advances that have occurred, the development of novel analgesic medications with improved efficacy and safety has lagged and there have been few successes. At present, the only analgesics that are in widespread use are acetaminophen, non-steroidal anti-inflammatory drugs, and opioids, all of which have only modest efficacy but potentially serious, life-threatening risks. Consequently, there is a compelling public health need for the development of improved treatment interventions.

Unfortunately, numerous treatments examined in recent randomized clinical trials have failed to show efficacy. Although explanations for these results certainly include the possibility that some of these treatments are not efficacious, a considerable number of trials of known efficacious treatments have also been negative, which raises questions about the ability of clinical trials to distinguish efficacious analgesic treatments from placebo or less efficacious treatments (i.e., assay sensitivity). Patient characteristics, clinical trial designs, outcome measures, approaches to data analysis, and statistical power may all play a role in accounting for difficulties in demonstrating the benefits of efficacious treatments. The identification of specific clinical trial characteristics associated with greater assay sensitivity and the development of outcome measures with greater validity can provide the foundation for an evidence-based approach to the design of clinical trials, not only of pain treatments but also in other therapeutic areas.

To address unmet needs for improved treatments for pain, sedation and anesthesia, addiction, and peripheral neuropathy, the FDA has awarded a 5-year cooperative agreement to the University of Rochester School of Medicine and Dentistry to support the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership (PPP). ACTTION is a multidisciplinary collaboration comprised of individuals from academia, government agencies, patient advocacy organizations, and industry that identifies, prioritizes, and supports research projects and other initiatives to achieve this objective.

The specific aims of the research activities that will be conducted by ACTTION are to: (1) continue to access, transform, harmonize, and pool patient-level data from Phase 2 and 3 trials made available by FDA; (2) conduct analyses of individual participant-level data and study-level publicly-available trials to provide (a) an evidence base for improving the assay sensitivity, informativeness, and interpretation of clinical trials, (b) investigate different strategies for accommodating missing data, and (c) address additional statistical issues in the analysis of clinical trials; (3) develop novel outcome measures for clinical trials, for example, composite measures of pain and physical functioning and pain and use of rescue analgesics; and (4) develop and qualify novel clinical outcome assessments for pain intensity



and—depending on the outcomes of systematic reviews and consensus meetings—for sedation, addiction, and peripheral neuropathy, resources permitting. In addition, ACTTION will continue spearheading the development of evidence-based diagnostic criteria for use as eligibility criteria in clinical trials and in translating clinical trial results to clinical practice. These research projects have the aim of improving clinical trial methods to increase their assay sensitivity and informativeness. The knowledge gained from these studies and ACTTION’s other activities has the potential to inform and accelerate the development of improved treatments for pain, anesthesia and sedation, addiction, and peripheral neuropathy

This document, the Governance Structure and By-laws for ACTTION, presents the framework for how the PPP (1) will be organized and governed; (2) will include stakeholders from professional organizations, academia, industry, and government agencies; and (3) will generate financial support to achieve its mission and objectives.

2. MISSION STATEMENT

The mission of the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership with the United States Food and Drug Administration (FDA) is to identify, prioritize, sponsor, coordinate, and promote innovative activities — with a special interest in optimizing clinical trials — that will expedite the discovery and development of improved analgesic, anesthetic, addiction, and peripheral neuropathy treatments for the benefit of the public health.

3. ORGANIZATION

The ACTTION PPP is organized as an independent organization of participants from public and private organizations including academia, professional societies, industry, and government agencies that are committed to the development of safe and effective pain, anesthesia and sedation, addiction, and peripheral neuropathy treatments for improving the public health. The policies and procedures for public-private partnerships and consortia of the FDA Center for Drug Evaluation and Research should be consulted for a description of the roles and responsibilities of FDA employees interacting with outside organizations such as the ACTTION PPP (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM532571.pdf>).

4. HEADQUARTERS

The Headquarters of the ACTTION PPP shall be located at the University of Rochester School of Medicine and Dentistry. In any circumstance in which the Director of ACTTION is at another institution, then the Headquarters of the ACTTION PPP shall be located at the Director’s institution. The Headquarters will



comprise the ACTTION Coordinating Center (see Section 5.4) and will be where all revenues and expenses of the PPP shall be maintained, transacted, recorded, monitored, and audited in specifically designated accounts as managed by the administrator of the relevant department or center and verified by a designated individual from the institutional grants and contracts office or other relevant unit assigned to the PPP. If the ACTTION Headquarters is not able to support any specific Coordinating Center activities (e.g., data management and analysis), such activities can be conducted elsewhere with oversight provided by the Headquarters and Coordinating Center.

In the event that the Director of ACTTION is no longer able to serve in that capacity, the Associate Director will automatically become the new Director, and all ACTTION funds and other resources will be transferred to the new ACTTION Headquarters at his or her institution as soon as possible. In the event that both the Director and the Associate Director are no longer able to serve in those capacities, the other members of the ACTTION Steering Committee (see Section 5.1.1) — that is, the ACTTION Assistant Directors; Chief Biostatistician; Program Director; Co-Chairs representing professional societies; Chairs of the peripheral neuropathy, addiction, and sedation/anesthesia consortia; and FDA representatives — will convene and appoint a new ACTTION Director and Associate Director whose terms will continue until the end of the current ACTTION cooperative agreement with the FDA.

5. GOVERNANCE STRUCTURE

5.1. Executive Committee (EC)

The EC will be responsible for identifying, coordinating, and prioritizing all activities of the ACTTION Coordinating Center (see section 5.4), including any Oversight Committee (see Section 5.2) recommendations regarding ACTTION research projects and other activities. The ACTTION Director and Associate Director, respectively, will serve as Chair and Vice-Chair of the EC.

Because of the broad scope of ACTTION, it is imperative that multiple health disciplines are involved in the development of improved research methods and ultimately treatments with greater efficacy and safety. To address this goal, the EC includes a set of Co-chairs who have been appointed by seven professional organizations that have been involved in ACTTION since its inception, as listed directly below. Additional professional and patient advocacy organizations may participate in the activities of ACTTION by providing liaisons who serve as members of the ACTTION EC, as also listed directly below.

Professional Societies and Other Organizations Represented on the ACTTION Executive Committee
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<i>Professional societies with Co-chairs</i>
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- American Pain Society (APS)
- American College of Rheumatology (ACR)
- American Society of Anesthesiologists (ASA)
- American Academy of Neurology (AAN)
- Osteoarthritis Research Society International (OARSI)
- Outcome Measures in Rheumatology (OMERACT)
- American Academy of Pain Medicine (AAPM)

Affiliated organizations with liaisons

- American Chronic Pain Association (ACPA)
- Chronic Pain Research Alliance (CPRA)
- German Research Network on Neuropathic Pain (DFNS)
- International Association for the Study of Pain (IASP)
- National Institutes of Health (NIH)
- Veterans Health Administration (VA)

Each of the EC Co-chairs representing the professional organizations will be responsible for representing the views of that professional organization and informing that organization of ACTTION initiatives and accomplishments; each of these Co-chairs will have one vote on behalf of that organization in any circumstances in which the EC members are asked to vote. These Co-chairs will be appointed by the professional society and may serve for an unlimited amount of time on the EC or may be replaced at the discretion of the society.

Professional organizations may apply for a seat on the EC by submitting a written request to the Director of ACTTION. The EC will review the structure and mission of the requesting professional organization and will vote on the inclusion of that organization by a majority vote.

The EC will ensure that all participants associated with ACTTION and its activities are in compliance with Federal regulations to the extent required and also with the applicable conflict of interest policies of the institutions where any ACTTION research studies or activities are conducted. In addition, all individuals associated with ACTTION must notify the EC whenever there is a potential conflict of interest that could impact their ACTTION activities or responsibilities, and the EC must then act to resolve the potential conflict of interest in advance. For example, if the EC is considering awarding junior investigator fellowships and a mentee of one of its members has applied for such support, that EC member must notify the EC and must be recused from any consideration of the application.

It is expected that decisions will be made by consensus of the members of the EC. In the event that a consensus cannot be achieved (e.g., prioritization of research studies, inclusion of new professional organizations in the EC), the Chair of the EC will first ensure that there is an established quorum of the EC membership, defined as two-thirds of its members. Each EC member shall have one vote, and a simple



majority vote, defined as a minimum of 51% of an established quorum of the EC, will be used to make any decisions for which consensus cannot be attained.

Meetings of the EC will typically occur as quarterly teleconferences and on an as-needed basis. Minutes will be prepared by the ACTTION Program Director and will be distributed to all members of the EC in advance of the next teleconference, during which the minutes will be reviewed, revised if necessary, and then approved.

5.1.1. Steering Committee

The ACTTION Director, Associate Director, Assistant Directors, Chief Biostatistician, Program Director, Co-Chairs representing professional societies, Chairs of the peripheral neuropathy, addiction, and sedation/anesthesia consortia, and FDA representatives will constitute an ACTTION Steering Committee within the larger EC that is responsible for authorizing major ACTTION commitments and for conducting quarterly budget reviews and providing authorization for all payments using ACTTION's unrestricted industry funds (the FDA representatives to the Steering Committee do not participate in approval of the industry support budget).

5.2. Oversight Committee (OC)

In accord with the Funding Opportunity Announcement for the ACTTION cooperative agreement, the OC was established to provide strategic support in fulfilling the overall scientific mission of the ACTTION PPP, specifically by providing advice and guidance to the EC and Coordinating Center in identifying and prioritizing all of ACTTION's activities. In addition, on an annual basis, the OC will conduct systematic evaluations of the progress being made in fulfilling ACTTION's mission. Regularly scheduled meetings of the OC are conducted by teleconference and on an in-person basis as needed. The members of the ACTTION OC (as of the date of approval of this document) are: Howard Fields, MD, PhD (University of California San Francisco); Jennifer Haythornthwaite, PhD (Johns Hopkins University); Sean Mackey, MD, PhD (Stanford University); James Rathmell, MD (Harvard University); and Kenneth Schmader, MD (Duke University).

5.3. Consortia, Collaborations, and Working Groups

The organizational structure of ACTTION includes multiple Consortia, Collaborations, and Working Groups. The major efforts of these ACTTION activities (as of the date of approval of this document) are listed directly below.

Consortia

Consortium for Addiction Research on Efficacy and Safety (CARES)

- Chair: Eric Strain, MD (Johns Hopkins University)
- Outcome measures and clinical trial designs for stimulant addiction treatments



Consortium on Clinical Endpoints and Procedures for Peripheral Neuropathy Trials (CONCEPPT)

- Chair: Roy Freeman, MD (Harvard University)
- Outcome measures and clinical trial designs for disease-modifying treatments for peripheral neuropathy

Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research (SCEPTER)

- Chair: Denham Ward, MD, PhD (University of Rochester)
- Assessment of efficacy and safety and research design considerations for clinical trials of pediatric and procedural sedation products

Collaborations

ACTTION-American Pain Society Pain Taxonomy (AAPT) — Chronic Pain

- Development of a comprehensive, multidimensional evidence-based chronic pain taxonomy with structured diagnostic criteria for the major chronic pain conditions. This will be an ongoing effort in which the diagnostic criteria developed for the initial versions of AAPT will undergo iterative studies of reliability and validity that provide the basis for subsequent revisions.

ACTTION- American Pain Society –American Academy of Pain Management Pain Taxonomy (AAAPT) — Acute Pain

- Development of a comprehensive, multidimensional evidence-based acute pain taxonomy with structured diagnostic criteria for the major acute pain conditions. This will be an ongoing effort in which the diagnostic criteria developed for the initial versions of AAAPT will undergo iterative studies of reliability and validity that provide the basis for subsequent revisions.

Active Working Groups

Pain-Related Outcomes Transformations to Enhance the Conduct of Clinical Trials (PROTECCT)

- Development of training materials for patient-reported pain outcomes, and development and qualification of novel pain intensity outcomes for acute and chronic pain
Public Relations and Other Communication and Education Strategies (PROCESS)

- To disseminate the contributions of ACTTION and IMMPACT and thereby improve knowledge of the design, execution, analysis, and interpretation of clinical trials of pain treatments, 14 articles are being prepared and will be published as a Journal of Pain open-access supplement

Retrospective Evaluation of Patient-Level Information from Controlled Analgesic Trials of Efficacy (REPLICATE)



- With support from a 3-year FDA contract to conduct analyses of patient-level data from analgesic clinical trials submitted to the FDA, studies of (1) statistical aspects of analgesic trials (e.g., accommodation of missing data), (2) development and validation of composite outcome measures of pain and physical functioning and pain and rescue analgesic use, and (3) relationships between study subject characteristics and assay sensitivity

Safety and Benefit-Risk Reporting and Evaluation (SABRRE)

- Systematic reviews of reporting adequacy and methodologic aspects of published clinical trials, including primary efficacy outcomes, statistical analyses, adverse events, conflicts of interest, data and safety monitoring boards, and other characteristics, as well as specific studies of pediatric pain, cancer pain, and temporomandibular disorder clinical trials

5.4. Coordinating Center

The current ACTTION Coordinating Center is comprised of the following individuals: Director (Robert Dworkin, PhD, University of Rochester); Associate Director (Dennis Turk, PhD, University of Washington); Assistant Directors (Jennifer Gewandter, PhD, and Shannon Smith, PhD, University of Rochester; Kushang Patel, PhD, University of Washington), Chief Biostatistician (Michael McDermott, PhD, University of Rochester); and Program Manager (Cornelia Kamp, MBA, University of Rochester). These seven individuals oversee and implement the activities of the ACTTION PPP, as follows:

- Development of procedures for the identification, prioritization, and implementation of administrative activities.
- Overall management and provision of administrative coordination for all ACTTION activities.
- Specific project management activities as reviewed and approved by the EC and Steering Committee.
- Serving as the fiscal agent for ACTTION and conducting accounts payable and reporting functions on its behalf with the approval of the Steering Committee.
- Data management (including transformation, harmonization, and coding) and data analysis.
- Providing support for scientific workshops, IMMPACT consensus meetings, and other meetings, including preparation of meeting announcements and invitations, development of meeting agendas and transcripts, and coordination of travel, hotel, meals, and audio-visual support.
- Recruiting, evaluating, and employing candidates for positions with ACTTION.

At the time of approval of this document, the administrative and budgetary support for the ACTTION Coordinating Center are provided by the Sponsored Research Center of the Department of Pharmacology and Physiology at the University of Rochester School of Medicine and Dentistry. Support for meetings and related activities are provided by Valorie Thompson, RN, President of Innovations



Consulting Group.

To keep all ACTTION participants and the public informed of the progress of the ACTTION PPP, a website is maintained (www.action.org). The ACTTION Director and Associate Director, with the support of the Coordinating Center, oversee the content and regular updating of this website. The website currently includes information about the following activities of ACTTION: mission, organizational structure, meetings, news, publications, various clinical trials databases and other resources, link to the IMMPACT website, and lists of professional societies and other organizations with representation on the EC.

5.5. Participation in ACTTION Activities

Participation in the ACTTION PPP will include individuals representing the major stakeholders involved in relevant research and other activities, including, but not limited to: academia; professional societies; interested regulatory and other governmental agencies; patient advocacy groups; the pharmaceutical, biologics, and device industries; and trade, contract research, and laboratory organizations. These participants will not be limited to United States representation, and will also include international entities.

The ACTTION PPP will seek broad involvement in its activities through the contributions of its participants and other experts in accomplishing its mission. Membership on various committees and working groups will require meaningful contributions, although the specifics of these contributions will vary for different members and projects. Industry involvement will typically be dependent on the provision of unrestricted financial support for the PPP and its activities. All participants and participating organizations in the PPP are expected to make meaningful contributions to specific ACTTION activities and projects, including but not limited to, data, technology-platforms, staff expertise, infrastructure, funding, and other resources.

6. FUNDING

All participants in the ACTTION PPP will have responsibility for attempting to secure funding for ACTTION and its activities. ACTTION will pursue funding from a variety of sources, including additional government grants and contracts from FDA and other government agencies, unrestricted support from industry, philanthropic contributions, royalties, and other miscellaneous revenue.

7. ANTI-TRUST GUIDELINES

The ACTTION PPP will handle all anti-trust issues in compliance with federal standards (Sherman Act 15 U.S.C. sect 1 *et seq*). Specifically, any indication of improper commercial bias or facilitation of collusion (directly or indirectly) associated with the legitimate scope of ACTTION activities could expose its members and other



participants to anti-trust risk. Issues may arise that could have anti-trust implications, which include but are not limited to:

- Use of the PPP unfairly to promote a particular technology or product or exclude another for commercial reasons; and
- Inappropriate sharing of confidential or competitively sensitive information of competing companies, including intellectual property, pricing, production, or innovative plans.

All participants in the ACTTION PPP and its activities will need to abide by guidelines based upon federal standards to prevent such risk, as follows:

7.1. Recommended Anti-trust Guidelines

- Private partners may freely conduct activities that do not infringe on intellectual property of other members and participants or intellectual property generated by the ACTTION PPP.
- No member shall take or seek action relating to the ACTTION PPP for purposes of excluding products or technology of competitors from the market or impeding research and development.
- The Director and Associate Director, with input from the EC as needed, must review and approve all public communication and data sharing activities.

7.2. Restricted Topics

The following is a list of restricted topics that should not be shared or discussed during any meetings, teleconferences, or events conducted under the auspices of the ACTTION PPP:

- Pricing, pricing policies, market shares, services of private partners.
- Intentions about commercial activities, including advertising, promotion, research and development outside the ACTTION PPP, or whether to deal with specific customers (including government programs).
- Speculation or prediction about commercial activities of private and publically traded partners in response to business or legislative developments.
- Discussion of any topic of commercial significance to competitors that may involve anti-trust compliance.

8. INTELLECTUAL PROPERTY GUIDELINES

Any attempt to establish broad rules for intellectual property protection in an initiative such as the ACTTION PPP are necessarily limited by the somewhat open-ended nature of the research projects and other activities that will be conducted. As a result, the following ACTTION policy on intellectual property has been designed to



establish general principles that are likely to apply to most of the anticipated activities but that also allows for flexibility depending on specific circumstances.

- All intellectual property or work products arising out of ACTTION are to be made freely available and not subject to proprietary intellectual property protection.
- Exceptions can be made to this general rule for specific work products that involve substantial resource investment by ACTTION or one or more ACTTION collaborators or grantees that justify the intellectual property protection of the work product. Exceptions would need to be approved by a two-thirds vote of the entire ACTTION EC.

9. DATA SHARING GUIDELINES

Sharing data from public and private partners is anticipated to expedite the work of the ACTTION PPP. Confidential scientific data may be shared by ACTTION PPP participants (including data directly from FDA), subject to intellectual property, anti-trust, data sharing, and FDA confidentiality policies and other federal laws.

Participants should not share data or other confidential information about commercial activities with each other, particularly restricted topics (see section 7). The EC and legal counsel of the participants should be consulted on the appropriateness of:

- Data sharing; note that the FDA Office of Chief Counsel must approve all activities associated with sponsor data.
- Confidential and commercial information.
- Subject to foregoing precautions, if unaggregated, confidential, and competitively sensitive information or data are collected under the ACTTION PPP, such information should never be shared outside the project team and should be destroyed except when subject to federal regulations.
- Any data collected from private participants should include statements that the information will be handled in conformity with guidelines of the ACTTION PPP.
- Any personal information from participants in ACTTION-sponsored research will meet all applicable HIPAA standards.

10. PUBLICATION POLICY

The ACTTION PPP Publication Policy is designed to promote the scientific and technical accuracy and integrity of all ACTTION PPP publications and ensure that appropriate credit is given to the authors and to other individuals who have contributed to the ACTTION PPP scientific efforts. In addition, ACTTION PPP participants are encouraged to carry out high-quality research and other scientific efforts and to publish their results in a timely manner in peer-reviewed journals and other appropriate outlets. By agreeing collectively in advance regarding how publication issues will be handled, future disagreement among ACTTION PPP participants will be minimized. This section presents ACTTION PPP's overall publications policy and provides for some flexibility. By way of definition, a



publication is any document submitted to a professional journal, any popular periodical, a scientific meeting, or for publication as a book chapter.

Publication of ACTTION PPP data and other activities undertaken without conforming to these policies is not permitted without prior written consent from the ACTTION PPP Director and Associate Director, with input from the EC as needed. None of the rules contained herein should be allowed to contravene the principles that: all individuals who have made substantial intellectual, scientific, and practical contributions to the work described in the manuscript should, when they agree, be credited as authors. All individuals credited as authors should deserve that designation, and the following guidelines should be followed.

- All manuscripts resulting from the ACTTION PPP should be published in peer-review journals and appropriate credit should be given to the ACTTION PPP.
- The ACTTION PPP publication policy will generally adhere to the authorship policies set out in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (International Committee of Medical Journal Editors).
- All authors listed on any ACTTION PPP publications should generally fulfill the requirements for authorship as set forth in the “authorship section” of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (specific requirements of journals may vary).
- ACTTION requires that all authors review the analysis and interpretation of data, and carefully review and provide approval for publication of the manuscript.
- The status of manuscripts in preparation will be reviewed at each ACTTION EC meeting as a standing agenda item.
- Final versions of all journal manuscripts should be submitted to PubMed Central immediately upon acceptance for publication.

Acknowledgements of specific contributions by individuals who do not qualify for authorship should be made for one or more of the following: statistical analysis; obtaining funding; administrative, technical, and materials support; and other contributions. In addition, all articles should acknowledge all support from the study sponsor and any other organizations providing financial support or other resources, such as data or clinical trial materials, as well as the ACTTION-PPP.

The EC will promote, facilitate, and monitor the timeliness of all publications of the ACTTION PPP. The EC will review, provide comments on, and approve all publications prior to submission, enlisting the special assistance of other ACTTION PPP participants whenever appropriate. Reviews will be conducted pursuant to the following general editorial responsibilities: (1) ensure that all ACTTION PPP publications preserve the scientific and scholarly integrity of the work; (2) correct factual and conceptual inaccuracies, if necessary; (3) safeguard the rights and confidentiality of volunteer participants; (4) prepare comments to assist collaborating



scientists in publishing papers of the highest quality and clarity; (5) avoid conflict with and/or duplication of other publications; and (6) ensure that the ACTTION PPP is appropriately acknowledged in the publication.

The ACTTION Coordinating Center will maintain an up-to-date bibliography and repository of all publications and presentations pertaining to the ACTTION PPP activities. The complete ACTTION bibliography will be maintained on the ACTTION website.

11. PUBLICITY, PRESS RELEASES, AND INTERVIEWS

A press release is defined as a document provided to radio, television, newspapers, popular periodicals, or scientific journals. An interview is any discussion with a member of the press, a science writer, or a radio or television commentator, which in turn provides information for public dissemination.

Press releases and interviews should not be initiated by individual ACTTION PPP participants without prior authorization from the ACTTION PPP Director and Associate Director. All press releases must be reviewed and approved by the ACTTION Director and Associate Director and FDA (if named within the press release) and any other named entities (e.g., pharmaceutical companies and other industry and non-industry sponsors) prior to release.

Should a participating ACTTION PPP participant be solicited for information other than as that detailed above, the individual and/or organization should refer the soliciting party to ACTTION Director and Associate Director.

12. AMENDMENTS and DISSOLUTION OF THE ACTTION PPP

Amendments to the Governance Structure and Bylaws of the ACTTION PPP may be proposed by any voting member of the EC, must be made in writing, must be signed by four other voting members of the EC, and must be submitted to the Director of the ACTTION PPP at least two months prior to a meeting of the EC. The Director will make sure that the proposed amendment is distributed to the entire EC at least 10 days prior to the next EC teleconference. At the next EC teleconference, the proposed amendment will be considered and voted upon. Amendments must be approved by a simple majority vote (see Section 5.1) of an established quorum of the voting members of the EC.

The dissolution of the ACTTION PPP will be decided by an affirmative vote by written ballot by a simple majority vote (see Section 5.1) of an established quorum of the voting members of the ACTTION PPP EC.