GOVERNANCE STRUCTURE and BY-LAWS

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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, anesthesia, addiction, and peripheral neuropathy, beginning in 2010, the United States Food and Drug Administration (FDA) awarded two contracts and two 5-year cooperative agreements 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. Since then, ACTTION has attracted additional funding support through its various initiatives. 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 aims of the research activities that are being conducted by ACTTION are to: (1) conduct analyses of individual participant- and study-level data from clinical trials to provide an evidence base for improving the assay sensitivity, informativeness, and interpretation of clinical trials, including addressing statistical issues in the analysis of clinical trials; (2) develop and qualify novel clinical outcome assessments and biomarkers for clinical trials, for example, novel pain intensity ratings and predictive biomarkers. In addition, ACTTION has spearheaded 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 activities have the aim of improving clinical trial methods to increase their assay sensitivity and informativeness. The knowledge gained from these and other ACTTION activities has informed and potentially accelerated the development of improved treatments for pain, anesthesia, addiction, and peripheral neuropathy.

ACTTION is a not-for-profit unincorporated association formed to advance the missions set forth in this document. This document, the ACTTION Governance Structure and By-laws, presents the framework for how ACTTION (1) is organized and governed; (2) includes stakeholders from professional societies, academia, industry, patient advocacy organizations, and government agencies; and (3) generates and maintains intellectual property and financial resources 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, and addiction treatments for the benefit of the public health.

3. ORGANIZATION
ACTTION is an independent unincorporated voluntary association of participants from national and international public and private organizations -- including professional societies, academia, industry, patient advocacy organizations, and government agencies -- who are committed to the development of safe and effective pain, anesthesia, and addiction 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 ACTTION (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM532571.pdf).

4. HEADQUARTERS
The ACTTION Headquarters is located at the University of Rochester School of Medicine and Dentistry. The Headquarters comprises the ACTTION Management Committee and is where all revenues, expenses and other disbursements, and finances are maintained, transacted, recorded, monitored, and audited in specifically
designated accounts as authorized by the Management Committee and verified by a designated individual from the University of Rochester assigned to ACTTION. If the ACTTION Headquarters is not able to support any specific activities (e.g., data management and analysis), such activities can be conducted elsewhere with oversight provided by the Management Committee.

At the time of approval of this document, budgetary support for ACTTION is provided by the Sponsored Research Center of the Department of Pharmacology and Physiology and by the Department of Anesthesiology and Perioperative Medicine at the University of Rochester School of Medicine and Dentistry. Administrative and logistical 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 its progress, a website is maintained (www.acttion.org). The ACTTION Director and Co-Director, with the support of the Management Committee, 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 trial databases and other resources, a link to the website of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), lists of professional societies and other organizations with representation on the Executive Committee (EC), and sources of financial support.

5. GOVERNANCE STRUCTURE

5.1. Management Committee

The ACTTION Management Committee consists of the following seven individuals: Director Robert Dworkin, PhD (University of Rochester), Co-Director Dennis Turk, PhD (University of Washington), and Associate Directors Robert Edwards, PhD (Harvard University), Jennifer Gewandter, PhD (University of Rochester), Michael McDermott, PhD (University of Rochester), Bryce Reeve, PhD (Duke University), and Denham Ward, MD, PhD (University of Rochester). These individuals oversee and implement the activities of ACTTION, 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 Executive and Steering Committees.
- Serving as the intellectual property and fiscal representative for ACTTION and conducting reporting functions and authorizing accounts payable on the basis of reviews and recommendations provided on a quarterly basis by the Steering Committee.
- Providing support for scientific workshops, IMMPACT consensus meetings, and
other meetings, including preparation of meeting announcements and invitations, development of meeting agendas, transcripts and draft manuscripts, and coordination of travel, hotel, meals, and audio-visual support.

- Recruiting, evaluating, and employing candidates for positions with ACTTION.

The ACTTION Management Committee has overall management oversight and financial responsibility for all of ACTTION’s intellectual and financial resources. This responsibility is retained by the Management Committee independent of any financial or other support received by ACTTION, including but not limited to support from industry and grants and contracts from government agencies, including FDA and the United States National Institutes of Health (NIH).

If the Director of ACTTION becomes unable to serve in that capacity, the Co-Director will automatically become the new Director. In the event that both the Director and the Co-Director cannot serve in those capacities, the other members of the ACTTION Management Committee will convene, and in consultation with the ACTTION Steering Committee, will appoint a new ACTTION Director and Co-Director.

5.2. Executive Committee (EC)

The EC will be responsible for identifying, coordinating, and prioritizing ACTTION’s research and other activities. The ACTTION Director and Co-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 nine professional organizations, 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.

<table>
<thead>
<tr>
<th>Professional Societies and Other Organizations Represented on the ACTTION Executive Committee</th>
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<tr>
<td><strong>Professional societies with Co-Chairs</strong></td>
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<tr>
<td>• American Academy of Neurology (AAN)</td>
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<td>• American Academy of Pain Medicine (AAPM)</td>
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<td>• American Academy of Pediatrics (AAP)</td>
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<td>• American College of Rheumatology (ACR)</td>
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<tr>
<td>• American Society of Anesthesiologists (ASA)</td>
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<td>• American Society of Regional Anesthesia and Pain Medicine (ASRA)</td>
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<td>• Osteoarthritis Research Society International (OARSI)</td>
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<td>• Outcome Measures in Rheumatology (OMERACT)</td>
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<tr>
<td>• United States Association for the Study of Pain (USASP)</td>
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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)
- United States National Institutes of Health (NIH)
- United States 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 position on the EC by submitting a written request to the Director of ACTTION, who will review the structure and mission of the requesting professional organization and will determine, in consultation with the Management and Steering Committees, whether that organization should be invited to appoint a Co-Chair or liaison to the EC.

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 Management Committee 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 Management Committee and must be recused from any consideration of the application.

It is expected that decisions not relegated to the Management Committee or Steering Committee will be made by consensus of the members of the EC. In the event that a consensus cannot be achieved, the Chair of the EC will first ensure that there is a quorum of two-thirds of the EC membership. Each EC member shall have one vote, and a simple majority vote, defined as a minimum of 51% of two-thirds of the EC membership, 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 Director of Operations 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.

5.3. Steering Committee

The ACTTION Director and Co-Director, five Associate Directors, Directors of Preclinical Research, Communications, Operations, and Program Evaluation, Co-Chairs representing professional societies, Consortium Chairs, and FDA representatives will constitute the ACTTION Steering Committee within the larger EC. The Steering Committee is responsible for providing quarterly reviews and recommendations regarding ACTTION’s major financial commitments and payments of meeting, research, and other expenses by the ACTTION Headquarters and Management Committee from ACTTION’s non-governmental funds (FDA representatives to the Steering Committee do not participate in approval of the industry support budget).

5.4. Oversight Committee

The Oversight Committee was established to provide strategic support in fulfilling the overall scientific mission of ACTTION, specifically by providing advice and guidance to the Management Committee and EC in identifying and prioritizing all of ACTTION’s activities. In addition, on an annual basis, the Oversight Committee will conduct systematic evaluations of the progress being made in fulfilling ACTTION’s mission. Regularly scheduled meetings of the committee are conducted by teleconference and on an in-person basis as needed. The members of the ACTTION Oversight Committee (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).

5.5. Consortia, Collaborations, and Working Groups

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

<table>
<thead>
<tr>
<th>Consortia</th>
<th>I. Consortium for Addiction Research on Efficacy and Safety (CARES)</th>
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<tr>
<td></td>
<td>Chair: Eric Strain, MD (Johns Hopkins University)</td>
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<tr>
<td></td>
<td>Clinical trial methods and outcomes for substance use disorders</td>
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<td></td>
<td>II. Consortium on Clinical Endpoints and Procedures for Peripheral Neuropathy Trials (CONCEPPT)</td>
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• Chair: Roy Freeman, MD (Harvard University)
• Diagnostic criteria for peripheral neuropathy

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

• Chair: Lena Sun, MD (Columbia University)
• Research design recommendations for clinical trials of pediatric ICU sedation products

Collaborations

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

• Publication of multidimensional evidence-based taxonomies and structured diagnostic criteria for the major acute and chronic pain conditions.

Most Active Working Groups

I. Pain-Related Outcomes Transformations to Enhance the Conduct of Clinical Trials

• Development and qualification of novel clinical outcome assessments and biomarkers, including:
  1. QUALITE-Pain: Qualified for Therapeutic Evaluations of Pain
  2. Boston-ACTTION Bedside QST
  3. PROGRESE: Patient-Reported Outcomes for Global Ratings of Effectiveness and Side Effects
  4. FORCAST: Focused Opioid Research Craving Assessment for Substance Use Treatment
  5. PAACT: Physical Activity Accelerometry Assessment for Analgesic Clinical Trials

II. Addressing Disparities in the Distribution and Assessment of Pain and its Treatments

• Systematic reviews of disparities in pain research

III. Preclinical Pain Research Consortium for Investigating Safety and Efficacy

• Multi-lab (5 US, 2 Canadian) study to examine inter-lab reproducibility of preclinical pain assays

IV. Retrospective Evaluation of Patient-Level Information from Controlled Analgesic Trials of Efficacy

• Analyses of patient-level data from analgesic clinical trials, including analyses of
heterogeneity among patients in treatment effects and in benefit-risk profiles

* The American Pain Society ceased operations in June 2019, a few years after each of these two collaborative projects began

5.6. Participation in ACTTION Activities

Participation in ACTTION 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 government agencies; patient advocacy groups; the pharmaceutical, biologics, and device industries; and trade, contract research, and laboratory organizations. These participants will include national and international entities.

ACTTION 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 ACTTION and its activities. All participants and participating organizations are expected to make meaningful contributions to specific ACTTION activities and projects, including but not limited to, data, expertise, infrastructure, funding, and other resources.

6. FUNDING

All participants in ACTTION can assist with attempting to secure funding for ACTTION and its activities. ACTTION will pursue funding from a variety of sources, including government grants and contracts from FDA and other government agencies (e.g., NIH), unrestricted support from industry, philanthropic contributions, royalties, and other miscellaneous revenue.

ACTTION funds that originate from grants and contracts from government agencies (e.g., FDA, NIH) are subject to standard Facilities and Administrative (F & A) costs. ACTTION funds that do not originate from government sources (e.g., support from industry) are not subject to F & A costs. F & A costs are not levied on such funds nor are they paid to outside universities, organizations, agencies, or other groups. A quarterly budget review conducted by the ACTTION Management Committee based on recommendations from the Steering Committee authorizes all payments by the ACTTION Headquarters from these ACTTION non-government funds. At the University of Rochester, these ACTTION funds are held by the University as a custodian of the funds.
7. ANTI-TRUST GUIDELINES

ACTTION 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 ACTTION 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 ACTTION 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 ACTTION.
- No member shall take or seek action relating to ACTTION for purposes of excluding products or technology of competitors from the market or impeding research and development.
- The Director and Co-Director, with input from the EC as needed, must review and approve all public communications 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 ACTTION:

- Pricing, pricing policies, market shares, services of private partners.
- Intentions about commercial activities, including advertising, promotion, research and development outside ACTTION, 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 for a voluntary association such as ACTTION 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.

- Intellectual property or work products arising out of ACTTION will typically 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. Such exceptions would need to be approved by the ACTTION Management Committee.

9. DATA SHARING GUIDELINES

Sharing data from public and private partners is anticipated to expedite the work of ACTTION. Confidential scientific data may be shared by ACTTION 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 Management Committee and legal counsel of the participants should be consulted on the appropriateness of:

- Data sharing; note that FDA must approve all access to and analyses of sponsor data received from FDA as a result of the award of contracts or through other means.
- Confidential and commercial information.
- Subject to foregoing precautions, if unaggregated, confidential, and competitively sensitive information or data are collected by the ACTTION public-private partnership, such information should never be shared outside the project team.
- Any data collected from private participants should include statements that the information will be handled in conformity with ACTTION guidelines.
- Any personal information from participants in ACTTION-sponsored research will meet all applicable HIPAA standards.

10. PUBLICATION POLICY

The ACTTION Publication Policy is designed to promote the scientific and technical accuracy and integrity of all ACTTION publications and ensure that appropriate credit is given to the authors and to other individuals who have contributed to the
ACTTION scientific efforts. In addition, ACTTION 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 participants will be minimized. This section presents ACTTION’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 data and other activities undertaken without conforming to these policies is not permitted without prior written consent from the ACTTION Director and Co-Director, with input from the Management Committee 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 ACTTION’s activities or support should be published in peer-review journals and appropriate credit should be given to ACTTION.
- The ACTTION publication policy generally adheres 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 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 data analyses and interpretation, 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: 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 ACTTION.

The EC will promote, facilitate, and monitor the timeliness of all ACTTION publications. The EC will review, provide comments on, and approve all publications prior to submission, enlisting the special assistance of other ACTTION participants.
whenever appropriate. Reviews will be conducted pursuant to the following general editorial responsibilities: (1) ensure that all ACTTION 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 ACTTION is appropriately acknowledged in the publication.

The ACTTION Management Committee will maintain an up-to-date bibliography and repository of all publications and presentations pertaining to ACTTION 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 participants without prior authorization from the ACTTION Director and Co-Director. All press releases must be reviewed and approved by the ACTTION Director and Co-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 participant be solicited for information other than as that detailed above, the individual and/or organization should refer the soliciting party to the ACTTION Director and Co-Director.

12. AMENDMENTS and DISSOLUTION OF ACTTION

Should the FDA requirement for, or interest in, continuing a public-private partnership with ACTTION change, ACTTION will use its good faith efforts to amend its Governance Structure and By-laws to conform to any new FDA requirement.

Should the FDA wish to end its public-private partnership with ACTTION, ACTTION will continue as an unincorporated association supported by the other funding it is able to attract through its efforts.

Amendments to the Governance Structure and By-laws of the ACTTION may be proposed by any member of the Steering Committee and must be made in writing and submitted to the Director of ACTTION. The Director will ensure that the proposed amendment is distributed to the entire Steering Committee and the proposed amendment will be considered and voted upon by the Steering Committee.
by e-mail. Amendments must be approved by a simple majority vote of a quorum of at least two-thirds of the members of the Steering Committee.

Dissolution of the ACTTION public-private partnership will be decided by an affirmative vote by written ballot of a two-thirds majority of all members of the ACTTION Management Committee (e.g., at least 5 of the 7 current members).