

## ACNS Guidelines Process Approved March 2023

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# Proposal of New or Revised Guidelines

\*note that throughout this document, the term "guideline" is used to mean any clinical practice guidelines, consensus statements, technical standards, and any other ACNS guidance document

## 1. Proposing New Guideline Topics

- 1.1. Any ACNS member in good standing may propose a new guideline
- 1.2. Proposals must be submitted in writing, and include the following details:
  - 1.2.1. Title
  - 1.2.2. Type of document (e.g., clinical practice guideline on indications, technical standard, consensus statement on terminology, etc.)
  - 1.2.3. Synopsis: should describe succinctly the need for the document, why ACNS is the appropriate group to issue the guidance, and to define the scope of the proposed work
  - 1.2.4. Details of relevant existing guidelines: any existing guidelines or other guidance that has any overlap with the proposed topic, whether from ACNS or from other groups, should be detailed, including name of issuing body, date of publication/last revision, summary of scope, and how the proposed guideline would differ.
  - 1.2.5. Outline of protocol: the planned approach should be outlined, including methodology that will be used
  - 1.2.6. Anticipated collaborations outside ACNS: if the proposal is for a guideline to be developed jointly with another society, or that will be presented for endorsement by any other group, full details of that process must be included.
- or that will be presented for
- 1.3. Proposed authors
  - 1.3.1. The lead and senior authors will be nominated within the proposal
    - 1.3.1.1. Qualifications of the lead and senior authors should be provided in short statements at the time of proposal, with a statement of commitment and agreement with proposed timeline and Col policy if selected
    - 1.3.1.2. While consideration will be given to the nominated lead and senior authors in a proposal, selection of lead and senior authors ultimately rests with the GC and ACNS Council
  - 1.3.2. A list of proposed co-authors/writing group may be included at the initial proposal, or may be submitted for approval after the project is approved [see Authorship document]
- 1.4. Requested resources or special circumstances
  - 1.4.1. If any special considerations are required, such as in methodology to align with a co-sponsoring organization, this should be included in the initial proposal
  - 1.4.2. If any relevant resources have been identified or are requested, these should be identified in the proposal. (example: specifying that the proposed lead author can obtain medical librarian services without charge, request for any software fees, request to procur external methodologist expertise)
- 1.5. A timeline for the proposed work should be given, including anticipated dates of key milestones

## 2. Proposing Revision of Existing Guidelines

- 2.1. Guidelines may be identified for revision by the GC or by ACNS members
  - 2.1.1. When a guideline is identified for revision by GC, members may be invited to submit proposals for the revision
  - 2.1.2. Council may choose to solicit proposals by an announcement to the membership for specific revisions
- 2.2. Proposals should include all the details above, plus an explanation of why the current guideline needs revision
- 2.3. It is recommended, though not required, that either the senior or lead author of the existing guideline remain involved in the proposed revision, and that at least one new senior or lead author be proposed for the revision.
- 2.4. It is recommended that the proposed author group include at least 1/3 new members who were not authors on the existing version.

## 3. Evaluation of Proposals

- 3.1. GC co-chairs will conduct initial review of proposals, to ensure proposals are complete and to identify any overlap with existing or pending projects
- 3.2. GC co-chairs will advance complete proposals without overlap to the full GC for discussion and feedback.
  - 3.2.1. The GC may offer recommendations regarding any component of the proposal
  - 3.2.2. The GC may offer feedback regarding the proposed lead and senior author, and any other proposed co-authors
  - 3.2.3. The proposal author will have the opportunity to revise the proposal based on GC feedback and providing this revision to the GC for consideration

3.3. The GC will present proposals to Council with a recommendation regarding approval. Council or ExComm will approve proposals as per bylaws.

## 4. Prioritization of Proposals within GC

- 4.1. After a proposal is approved, it will need to be triaged for priority within GC work. This is in recognition of the resources required from GC to develop documents, including the Col process, GC member involvement in methodology, review panels, etc.
- 4.2. If additional resources are requested beyond GC operating budget, such as funds for external methodology support, these must be separately approved by ACNS Council. Even if a proposal is accepted, the budgetary request may remain pending for several months or longer, depending on Council decisions each budget cycle.

## 5. <u>Timely Progress of Guideline Developement</u>

- 5.1. A proposed timeline will be included in each new proposal. It is the responsibility of the lead and senior author to ensure steady progress to reach stated goals.
- 5.2. An update on the project's progress will be requested at least quarterly, for inclusion in GC status reports.
- 5.3. If quarterly updates are not submitted, or progress falls significantly behind initial timeline, the lead and senior author will be asked to provide a detailed progress report and specify any planned adjustments to achieve project goals.
- 5.4. If progress falls behind more than one year beyond the initial timeline, the lead and senior author will be asked to propose a revised timeline with specific plans for adjustment for discussion by GC and review by GC co-chairs. If a timely response is not received or the revision plan is of concern, the project will be referred for discussion by Council, which may vote to take steps that could include dissolution of the author group and/or replacement of the lead and senior authors.

# **ACNS Guidelines Conflict of Interest Disclosure & Resolution Policy**

The following Conflict of Interest Disclosure & Resolution policy shall apply to all members appointed to the ACNS Guideline Committee, as well as authors participating in the development of ACNS guidelines or consensus/professional/societal statements. This will apply to the ACNS Guideline committee immediately and to authors appointed from the date listed above. This policy will be subject to future revision as determined by the Guidelines Committee and/or ACNS Council.

#### Definitions

- A Commercial Interest is any entity developing, producing, marketing, re-selling, or distributing health care goods or services consumed by, or used by, patients.
- A Financial Relationship is a relationship in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds), gifts, in-kind contributions (including meals) or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. ACNS considers relationships of the person involved to include financial relationships of immediate family members. Not all financial relationships are necessarily conflicts of interest, but all financial relationships must be disclosed and will be reported to ensure transparency.
  - Speakers Bureau: A compensated role as a presenter for which any of the following circumstances are met: the company has a contractual right to dictate or control the content, the company created the slides/presentation for the speaker, or the presenter is expected to act as the company's agent or spokesperson for the primary purpose of disseminating company or product information.
  - Litigation work: Any financial or material research support or compensation from giving expert testimony, acting as a witness or consultant, or preparing an affidavit for any legal proceeding involving a Commercial Interest (do not include proceedings for individual patients)
- Relevant Financial Relationships: ACNS defines "relevant' financial relationships" as financial relationships in any amount occurring within the past 36 months.
- Conflict of Interest (COI): Circumstances create a conflict of interest when an individual has an opportunity to affect guidelines or consensus/professional/societal statements about topics relating to products or services of a commercial interest with which he/she has a relevant financial relationship (i.e. financial relationship with commercial interest in the past 36 months relevant to the subject matter of the guideline/statement.)
- Immediate family member(s): spouse/partner and first degree family members

#### **COI** Disclosure Process

#### Guideline Committee Membership

All individuals appointed to serve as members of the ACNS Guidelines will be asked to complete the ACNS Guidelines COI Disclosure Form at the time of their appointment and annually thereafter.

#### **Guideline Authors**

Lead authors on a guideline will provide to ACNS staff a complete list of authors proposed to participate in guideline development *prior* to their participation in any authorship activities. Individuals asked to participate as authors in development of an ACNS guideline must complete the ACNS Guidelines COI Disclosure Form at the time of their invitation and annually thereafter.

*Prior to participation in any authorship activities*, the Guidelines Committee co-chairs will review financial relationships disclosed by each author and will categorize those relationships as follows, taking into account the topic of the guideline when determining relevance of financial relationships, and potential resulting conflicts of interest. Those financial relationships found irrelevant to the topic of the proposed work will not be considered toward the below classifications:

- Level I The individual or immediate family member(s) have ownership interest in, or employment by, a *commercial interest* as defined above, and the financial relationship presents a COI with the topic of the proposed work.
- Level II The individual or immediate family member(s) have financial relationships that present COI for the topic of the proposed work including:
  - Service on board of directors, or > \$50,000 annually single entity *commercial interest* compensation for *litigation* work (defined above), for service on an advisory board, or for commercial grant support (company provides research funding to individual or individual's institution is provided funding for a study where the individual is named as a principal investigator).
  - Significant stock ownership (shares > \$50,000 in value or an equity interest in a privately held company > 5 percent. This only pertains to health care related stock managed by the individual, not health care related stock managed by another entity, i.e. mutual fund).
  - Serves on a *speakers bureau for a commercial interest* (defined above) relevant to the subject matter of the proposed work.
- Level III The individual or immediate family member(s) have financial relationships that present COI for the topic of the proposed work including:
  - Receives \$5,000-\$50,000 annually from a single source relating to *litigation work* (defined above), service on an advisory board, or commercial grant support (company provides research funding to individual or individual's institution is provided funding for a study where the individual is named as a principal investigator).
  - Receives royalties, consulting fees, and/or honoraria greater than \$2,500 per year from a single source or more than \$10,000 annually from all sources.
  - Receives gifts or in-kind contributions (including meals) greater than \$200 per occurrence.
  - Level IV No financial relationships or financial relationships not rising to the thresholds defined above.

Any changes to committee members' or authors' financial relationships during the course of the committee members' terms or an authors' involvement in the writing process should be reported to ACNS Guidelines Committee co-chairs immediately for review.

#### **COI Resolution Process**

#### Guideline Committee Membership

Individuals appointed to serve as members of the ACNS Guidelines Committee may not have any **Level I** financial relationships. ACNS staff will notify the President and Guidelines Committee chair/co-chairs of any individuals disclosing ownership or employment by a commercial interest and they will be dismissed from committee service.

Because it is difficult to anticipate all the topics that may be addressed by ACNS guidelines over the course of a committee member's appointment, and therefore the potential conflicts of interest that may result from financial relationships, Guidelines Committee members are permitted to have non-ownership/employment financial relationships. However, committee members with Level II conflicts will be required to recuse themselves from conversations that may arise related to guidelines topics, where relevant financial relationships, and therefore potential conflicts of interest exist.

#### **Guideline Authors**

Once relevant financial relationships have been reviewed and potential COI categorized by the Guideline Committee chair/co-chairs, authors' potential conflicts of interest will be resolved by limiting an individual's participation in development of a guideline or consensus/professional/societal statement as follows:

- Level I & II Individuals with Level I and II conflicts of interest may not serve as authors.
- Level III An individual may participate as an author with restrictions (see below). The total number of authors with Level III conflicts of interest may not exceed 1/3 of the authors on a given guideline or consensus/professional/societal statement.
- Level IV Individuals may serve as authors without restriction. Both the lead and senior authors must be categorized as Level IV (free of conflicts related to the subject matter of the guideline/consensus statement) and must remain conflict-free for 12 months following the publication of the guideline/consensus statement.

#### Mitigation process for Level III authors

- Level III individuals MAY NOT participate in the systematic review itself. They may help with providing a few key, relevant
  articles to test the literature search strategy.
- Level III individuals are allowed to formulate questions, participate in Delphi method, and assist in editing the written draft. Guideline Committee co-chairs may require that only Level IV individuals lead the formulation of recommendations in collaboration with Level III (the clinical experts on the panel who may be conflicted as defined above), such that the responsibility for the final presentation of evidence summaries and rating the quality of evidence rests with those individuals without Level III COI.
- If an individual changes from Level IV to Level III COI during guideline or consensus/professional/societal statement development, ACNS Guidelines Committee co-chairs will review the COI to determine that the COI policy, author roles, and author composition (i.e. total number of authors with Level III conflicts of interest may not exceed 1/3 of the authors) is not compromised.

After COI resolution and *prior to their participation in any authorship activities,* authors will be informed of any role restrictions and any post-publication restrictions on author activity and sign a written statement accepting conditions of participating in the Guideline development.

Authors MAY NOT for a one year period after guideline/consensus statement publication speak about the guideline on behalf of a commercial interest or serve as an expert witness about the guideline on behalf of a commercial interest if that company could be positively or negatively affected by care provided in adherence with the guideline.

Questions or disputes related to classification of conflicts of interest or method of resolution shall be directed to the ACNS Executive Committee for final decision.

#### Publication of Financial Relationships

All ACNS guidelines are published in ACNS's official journal, the *Journal of Clinical Neurophysiology* (JCN). JCN policy requires that industry support of any kind must be acknowledged.

The ACNS Guidelines Committee co-chairs will provide to lead authors for inclusion in the guideline manuscript and JCN disclosure form a summary of authors' financial relationships to include:

• the name of the author,

the name of the commercial interest, and

• the type of relationship.

JCN only publishes those relationships found to pose a potential conflict of interest. However, where an ACNS guideline is endorsed or jointly developed with other groups, broader disclosures including financial relationships deemed not to be relevant may be required.

#### **COI** Publication Template

Author conflicts of interest will be published as part of the guideline manuscript in the following format:

"It is the policy of ACNS to ensure balance, independence, objectivity and scientific rigor in development of its guidelines and consensus/professional/societal statements. As such, ACNS requires that anyone who is in a position to control the content of a guideline or consensus/professional/societal statement disclose all financial relationships with commercial interests. Should it be determined that a potential conflict of interest exists as a result of a financial relationship of an author, the ACNS Guidelines Committee takes steps to resolve the conflict.

Complete conflict of interest disclosure information is for the authors of this guideline follows below:

Author Name	Author Institution	Conflict of Interest
John Doe, MD	ABC University Medical School	XYZ Corporation (Speakers Bureau)
Jane Smith, PhD	ABC University Medical School	No relevant relationships

ACNS provides this information in the spirit of transparency and reminds readers that information about financial relationships alone is not enough to decide whether they are beneficial or improper and that the existence of financial ties with commercial interests (listed in table as Conflict of interest) does not automatically constitute undue influence or author misconduct."

# Authorship for ACNS Guidelines

## 1. <u>General</u>

- 1.1. The authors' group must consist of those with relevant expertise and experience in clinical roles for which the guidelines would apply
- 1.2. Diversity, including but not limited to: gender, career stage, race/ethnicity, institution, and location of authors, will be reviewed by Guideline Committee leadership prior to commencement of the guideline development; adjustments may be requested to enhance diversity of the author group.
- 1.3. Every author must comply with ACNS policies relevant to Conflicts of Interest (COIs) throughout the entirety of the development and writing process, and for 12 months after guideline publication [see separate document].
- 1.4. ACNS Membership Requirements
  - 1.4.1. ACNS membership is required for guideline participation by any author eligible for membership
  - 1.4.2. Professionals outside ACNS can be asked to either participate in guideline development or in review (*example: surgeons, anesthesiologists*)
- 1.5. Named authorship requires meaningful contribution to guideline development.
- 1.6. Reviewers will be acknowledged accordingly
- 1.7. All authors are expected to sign off on the entire guideline prior to publication

## 2. <u>Composition</u>

- 2.1. An author group should include the following members:
  - 2.1.1. One project lead
  - 2.1.2. One project senior author
  - 2.1.3. Multiple experts in the area of the guideline
    - 2.1.3.1. The scope and nature of the work will determine the number of authors. At least 5 total authors are required. Only in exceptional circumstances would more than 15 authors be required.
    - 2.1.3.2. A pediatric neurophysiologist if the guideline applies to pediatrics
    - 2.1.3.3. It is encouraged but not required to include a representative of other relevant stakeholder societies
  - 2.1.4. At least one member with expertise in relevant guideline development methodology. The Guidelines Committee may also suggest a candidate or outsource to a methodologist group.
  - 2.1.5. A representative from ASET
  - 2.1.6. A representative of the patient perspective. This may be a patient, a patient's family member, or representative from a patient group. In many cases, this representative may participate in select stages of the work, such as refinement of the topic and outline, and in drafting and review of the manuscript. They will be included on the list of authors.
- 2.2. The working group may include additional members who may make focused contributions and thus not be named authors, but rather acknowledged. This status should be explicit prior to the start of work. Examples include:
  - 2.2.1. A representative/s from other relevant societies if not meeting level of authorship
  - 2.2.2. A medical librarian if not meeting level of authorship

## 3. Author Proposal and Selection

- 3.1. Lead and senior author will be named in the proposal for the new/revised guideline and approved during the proposal selection process. [see separate document]
- 3.2. The lead and senior authors may propose a list of co-authors at the time of guideline proposal or after proposal is approved, but each co-author must be approved by the Guidelines Committee prior to the start of any work.
  - 3.2.1. Each proposed co-author must be an active ACNS member and complete financial relationship disclosures to be considered.
  - 3.2.2. Each proposed co-author should provide a paragraph stating their interest in the project, specifying their planned contribution, and agreeing to the proposed timeline for the work.
  - 3.2.3. Guidelines Committee leadership will approve or identify any needed changes to the co-author list. It is at the discretion of the Guidelines Committee co-chairs whether to seek input from the larger GC and/or ACNS Council.
- 3.3. Any changes to the author group after initial approval must be requested in writing of Guidelines Committee, including the reason for the change. These are subject to approval by Guidelines Committee leadership, who will seek input from the larger GC and/or ACNS Council.
  - 3.3.1. Author removals should include a statement from the individual requesting removal, or from the lead/senior authors requesting conflict resolution with possible removal of the author.

3.3.2. Addition of new authors or a change in lead or senior author requires written agreement from each of the current authors and approval as above.

## 4. Authorship Conflict Resolution

- 4.1. For all conflicts, attempts toward resolution should first be made within the author group, including involvement by the lead and senior author
- 4.2. When an authorship disagreement cannot be resolved internally, any member of the author group may request the Guidelines Committee to become involved in conflict resolution.
  - 4.2.1. This request should be in writing and briefly state the issue at hand
  - 4.2.2. Conflict resolution will be led by Guidelines Committee leadership, and may include the larger GC in the process.
- 4.3. Examples of issues which may require involvement of the Guidelines Committee for conflict resolution include (but are not limited to): removal of a non-participatory or otherwise ineligible author, selection of new authors or a change in lead/senior author when there is not consensus among the writing group, ethical or conduct concerns, etc.
  - 4.3.1. For concerns regarding insufficient participation to warrant authorship, consideration will be made for the statement of planned contribution made by the individual prior to start of work, with an opportunity for explanation of any extenuating circumstances that may apply.
  - 4.3.2. Potential resolution may include specific prescribed actions and/or timeline by which the individual must increase their contribution to warrant authorship, and/or a suggestion to switch from an author role to an acknowledged contributor, in alignment with journal standards.
- 4.4. ACNS Council will be advised of any conflict resolution requests and have the opportunity to review the process and outcomes.

## **ACNS Guideline Methodologies**

#### 1. Overview of types of Recommendations

ACNS provides recommendations regarding best practices to support members and the field of clinical neurophysiology (CNP). The focus of recommendations developed by ACNS is clinical neurophysiology as practiced in the United States, while recognizing they may support practice in other regions as well. ACNS issues three categories of recommendations:

#### **Technical Standards**

These detail best practices in how to perform CNP studies/procedures. Because there is limited (and sometimes no) direct evidence regarding technical specifications for some CNP studies/procedures, Technical Standards are distinct from evidence-based clinical guidelines. These recommendations consider any available evidence, and then are developed through expert consensus as detailed below.

#### **Clinical Guidelines**

Clinical guidelines are evidence-based, systematically developed recommendations for clinical practice. These adhere to recognized standards for transparency and reproducibility, employing a systematic review and grading of available evidence, acknowledging existing gaps in evidence, and using evidence as the basis for clear recommendations. Clinical guidelines include recommendations regarding indications for CNP studies/procedures and other aspects of clinical care.

#### **Consensus Statements**

In CNP clinical care and research, it can be useful to employ common terminology or other shared systems. These may evolve as evidence allows refinement of historical or conventional systems. Consensus statements should include a scoping review of relevant evidence, followed by a systematic approach to achieve consensus, as detailed below.

The standards outlined here apply to all new ACNS clinical recommendations from March 2023 onward, and will be applied to existing guidelines as they are revised going forward. The methodology for each type of recommendation is described below. Other ACNS relevant policies are detailed elsewhere and are available separately.

#### 2. Collaborative Guidelines

This document outlines the preferred methodology for development of ACNS documents. In some cases, collaboration with other groups may be employed to develop recommendations. Collaborations may take various forms, including: endorsement by other groups/societies of a guideline developed by ACNS, joint development of a guideline, or ACNS adaptation or endorsement of a guideline developed by another group. The methodology described here may be adapted as needed to facilitate such collaboration with partner groups/societies, with the approval of the ACNS Guidelines Committee and Council prior to initiating work. The expectation is that all guidelines endorsed, adopted, or jointly developed by the ACNS would meet a similarly stringent standard, although the selected methodology may be different. Prior to development of collaborative documents, agreement should be made regarding plans for publication of the final product.

#### 3. Methodology for Technical Standards

#### 3.1. Delineating Purpose and Scope

The proposal for a technical standard document should describe the need for recommendations in the area proposed, particularly in relation to current practice or other existing best practice documents. If other relevant documents exist, whether issued by ACNS or other relevant groups, the proposed relationship between the ACNS technical standard and existing guidance should be made explicit. The intended scope should include details such as relevant patient population and practice setting, and should make explicit if the recommendations would NOT apply in any specific circumstances (e.g., inpatient vs outpatient; neonates vs. children vs. adults, etc.).

#### 3.2. Review of Relevant Evidence

A scoping review should be performed to provide an overview of relevant evidence. This requires development of a protocol to ensure a rigorous and transparent approach. The PRISMA-ScR checklist can be a useful tool in developing and performing the scoping review. The assistance of a medical librarian in developing the search strategy may be helpful. Inclusion and exclusion criteria should be specified prior to the search. Data charting should be performed independently by at least two individuals, with

disagreements resolved by a third review and/or discussion among the reviewers. ACNS does not require the use of a specific software platform for management of the scoping review; the choice of tools will be at the discretion of the authors. The review should also gather existing recommendations or guidelines from other bodies that may be relevant to the topic. If a recent scoping or systematic review has been performed on the topic, the results of that work may be used as the basis for review of relevant evidence, with an update for any newer publications since the date of the last search.

## 3.3. Generating Consensus

A Delphi process should be used to generate consensus among the author group. The criteria for consensus should be established prior to initiating the Delphi process. Possible approaches include specifying a minimum number of rounds of voting, achieving a threshold consensus for single items (e.g., 85% agreement), reaching a mean threshold of agreement using a Likert scale (e.g. mean >7 on a 9 point scale) or other prespecified stopping criteria for when items will be dropped or established. In contrast with other consensus statements, a Technical Standard may conduct a modified Delphi process using smaller group of participants, and/or just the author group.

The results of the scoping review should be summarized and presented to all members of the Delphi panel prior to the first round. Each survey round should be anonymous, followed by controlled feedback to all panel members, and lead to revision of questions/statements as indicated. This process is iterative, with rounds repeated until consensus is achieved. Final recommendations should reflect those items that achieve consensus among the panel.

## 3.4. Drafting of Recommendations, Review, and Publication

The draft Technical Standard will subsequently be reviewed by select members of the Guidelines Committee (see "Review" policy), with an opportunity to incorporate feedback prior to review by ACNS Council. Upon Council approval, the guideline will be posted for public comment for a minimum of 30 days, concurrent with any relevant invited comments. After the public comment period, a revised Guideline will be sent to Council for final approval. All ACNS Guidelines are published in the Journal of Clinical Neurophysiology and available through the ACNS website.

## 4. Methodology for Clinical Guidelines

## 4.1. Delineating Guideline Scope

Proposals for guidelines should specify the intended goal and scope of the document. The proposal should specify the type of guideline intended- for example, regarding indications for a diagnostic test, the prognostic value of a particular set of CNP findings, or whether an intervention leads to improved outcomes. The relationship between the proposed guideline and any existing recommendations from other groups should be identified.

## 4.2. Framing PICO questions

After proposal approval, the authors should create PICO questions to guide a literature search and review of evidence. PICO questions specify the <u>Population relevant</u> to the question, the <u>Intervention under consideration</u>, the <u>Comparison standard</u>, and the <u>Outcome of interest</u>. A guideline typically will address five or fewer PICOs. References and resources with further details on PICO development are available from the Guidelines Committee.

## 4.3. Review of Evidence

After PICO questions are finalized, a systematic review of evidence to answer each question should be performed. This should be registered with PROSPERO and performed in a way that allows the authors to report the process and results by PRISMA standards. A medical librarian should assist with the search strategy. Search should include at least PubMed/Medline and EMBASE. Inclusion and exclusion criteria should be specified prior to the search. Title/abstract screening and full text review should be performed independently by at least two individuals, with disagreements resolved by a third review and/or discussion among the reviewers. ACNS does not require the use of a specific software platform for management of the systematic review; the choice of tools will be at the discretion of the authors.

Data abstraction should allow summary and synthesis of the available evidence, where possible. A meta-analysis may be performed, if applicable. Where the systematic review identifies a paucity of direct evidence, meta-analysis may not be possible. If a recent systematic review has been performed, those results may serve as the basis for the review of the evidence, with a search performed to identify any more recent evidence, and to identify any evidence relevant to PICOs not included in the prior review.

## 4.4. Evaluation of Evidence

GRADE criteria should be applied to grade the quality of evidence for each PICO. No specific software is required for this process, so long as a GRADE evidence table is generated. In instances where a guideline is developed in collaboration with another group that uses methodology other than GRADE (such as Classification of Evidence Schemes), the method for evaluating evidence must be selected prior to evaluation of the evidence, and approved by the Guidelines Committee if an alternative to GRADE is proposed.

## 4.5. Applying Evidence to Create Recommendations

The writing committee should consider the GRADE summary and evaluation of evidence prior to drafting recommendations. Recommendations should include a description of strength and specify alternatives where applicable. If insufficient evidence is available to support a recommendation for a particular PICO, this should be clearly stated with research priorities identified.

## 4.6. Review and publication of Clinical Guideline

The draft Clinical Guideline will subsequently be reviewed by select members of the Guidelines Committee, with an opportunity to incorporate feedback prior to review by ACNS Council. Upon Council approval, the guideline will be posted for public comment for a minimum of 30 days, concurrent with any relevant invited comments. After the public comment period, a revised Guideline will be sent to Council for final approval. All ACNS Guidelines are published in the Journal of Clinical Neurophysiology and available through the ACNS website.

## 5. Methodology for Consensus Statements

## 5.1. Delineating Purpose and Scope

The proposal for a Consensus Statement should describe the need for the document, particularly in relation to current practice or other existing best practice documents. If other relevant documents exist, whether issued by ACNS or other relevant groups, the proposed relationship between the ACNS Consensus Statement and existing guidance should be made explicit. The intended scope should be defined, including key circumstances which will not be addressed in the statement. The proposal should detail why a consensus statement, and not an evidence-based clinical guideline, is needed for this topic.

## 5.2. Review of Relevant Evidence

A scoping review should be performed to provide an overview of relevant evidence. This requires development of a protocol to ensure a rigorous and transparent approach. The PRISMA-ScR checklist can be a useful tool in developing and performing the scoping review. The assistance of a medical librarian in developing the search strategy may be helpful. Inclusion and exclusion criteria should be specified prior to the search. Data charting should be performed independently by at least two individuals, with disagreements resolved by a third review and/or discussion among the reviewers. ACNS does not require the use of a specific software platform for management of the scoping review; the choice of tools will be at the discretion of the authors. If a recent scoping or systematic review has been performed on the topic, the results of that work may be used as the basis for review of relevant evidence, with an update for any newer publications since the date of the last search.

## 5.3. Generating Consensus

A Delphi process should be used to generate consensus. The initial proposal should indicate the planned composition of the Delphi panel. For Consensus Statements, and in contrast to Technical Standards, it may be appropriate to include a larger panel beyond the author group, to ensure that representative viewpoints are included. The Delphi panel should include participants reflective of the diversity of experts on the topic, including representation of relevant practice settings, training backgrounds, and regional diversity; this is in addition to diversity among the author group. For Consensus Statements, Delphi panels may range in size from 11 participants to over 100. Plans to recognize panel members should be explicit at the time the panel is formed, such as specifying whether they will be acknowledged by name in the resulting manuscript, and/or stating distinctions between panel membership and authorship on the document.

The criteria for consensus should be established prior to initiating the Delphi process. The results of the scoping review should be summarized and presented to all members of the Delphi panel prior to the first round. Each survey round should be anonymous, followed by controlled feedback to all panel members, and lead to revision of questions/statements as indicated. This process is iterative, with rounds repeated until consensus is achieved. Final recommendations should reflect those items that achieve consensus among the panel.

## 5.4. Drafting of Recommendations, Review, and Publication

The draft Consensus Statement will subsequently be reviewed by select members of the Guidelines Committee (see "Review" policy), with an opportunity to incorporate feedback prior to review by ACNS Council. Upon Council approval, the guideline will be posted for public comment for a minimum 30 days, concurrent with any relevant invited comments. After the public comment period, a revised Guideline will be sent to Council for final approval. All ACNS Guidelines are published in the Journal of Clinical Neurophysiology and available through the ACNS website.

## **ACNS Guideline Review Process**

#### 1. Overview

- 1.1. Upon completion of a draft guideline, consensus statement or other similar document, internal and external review and input shall be incorporated as below, prior to publication
- 1.2. The goals this process are to intentionally seek and include additional perspectives, identify any opportunities to improve the document, and to clarify and streamline the pre-publication pipeline

#### 2. Internal Review Panel

- 2.1. The internal review panel consists of 3-5 members of the Guidelines Committee (GC) with expertise in the topic of the document under review.
  - 2.1.1. The GC chair(s) will call for volunteers for the review panel of a guideline/consensus statement, providing title and author list. GC members may nominate themselves or other members. The review panel shall be selected by the GC co-chairs.
  - 2.1.2. Inclusion of at least one junior member, within 5 years of completion of training, will be sought.
  - 2.1.3. At least one member must have more than 5 years experience beyond completion of training.
  - 2.1.4. If the GC co-chairs are unable to form a review panel solely from GC membership, they may invite other ACNS members to join the review panel, on an *ad hoc* basis. In these instances, the ad hoc members must declare financial relationships in accordance with the Col policy, with no relationships above level IV. [see document]
- 2.2. Review panel membership and input will be named; it will not be anonymous to authors
- 2.3. Reviewer panel members will not be named as authors for the guideline, but may be named in the acknowledgements upon publication.
- 2.4. The review panel discusses the draft and produces a panel report, identifying key strengths and any areas needing revision. The panel report may be a stand-alone report, or may include the draft with annotations in track change mode.
- 2.5. The panel report will be sent to the lead and senior author to disseminate among the author group. The report will also be sent to the GC co-chairs.

#### 3. GC Review

- 3.1. The author group will respond to the panel report with a revision and point-by-point reply (similar to a journal response to reviewers in format). Each author of the document must review and approve this answer to reviewers before it can proceed.
- 3.2. This revision and reply will be send to the GC co-chairs, who can elected to accept the revision to forward to Council, or may call a full GC meeting to invite additional input.

#### 4. Review and Comment by Council

4.1. The draft will be circulated to Council for their review and feedback. This may be in conjunction with a scheduled Council meeting, or may be asynchronous between Council meetings with discussion and approval by ExComm.

## 5. Solicited External Reviews

- 5.1. In some instances, a document may warrant solicited review by another stakeholder or group (example: invited comment by other professional societies). This shall be invited by a representative of Council, with a proposed timeline to receive comments.
- 5.2. Solicitation of invited comments is optional

#### 6. Post for Public Comment

- 6.1. A revised draft incorporating feedback to date will be posted on the ACNS website, with an opportunity for public comment no less than 30 days.
- 6.2. ACNS membership will be given the opportunity to submit comments during this period.

#### 7. Revised Draft to Council for Approval

- 7.1. Following revisions based on public comment, lead authors will send the draft to GC leaders for final review.
- 7.2. GC may then pass on to Council for review with final approval by Council (or ExComm).

#### 8. Submission to JCN

8.1. The final, approved manuscript will be submitted to the Journal of Clinical Neurophysiology for publication, with any exceptions requiring Council approval in advance.

8.2. The manuscript may undergo additional peer review as per JCN policy

## ACNS Reaffirm & Update Process for Existing Guidelines

## 1. <u>Reaffirmation & Update Timelines</u>

- 1.1. All ACNS guidelines should be revisited every 5 years to ensure they remain current
  - 1.1.1. The order of guideline review will initially be set by GC co-chairs upon approval of this process, and then repeat every 5 years from the date of most recent reaffirmation or revision
- 1.2. The GC may recommend an earlier review if there has been a major change in a field/topic that warrants revisiting an existing guideline
  - 1.2.1. Earlier review may be proposed by any GC member and will be discussed at standing GC meetings

## 2. <u>Selection of Reviewers for Reaffirmation & Update</u>

- 2.1. A minimum of 3 reviewers for each document will be appointed by Guidelines Committee co-chairs
- 2.2. Lead and/or senior author of the existing guideline will be invited to participate, if they remain ACNS members
- 2.3. Other reviewers will include members of the GC with expertise in the relevant topic.
- 2.4. At the discretion of the GC co-chairs, ACNS members who are not members of the GC may be invited on an *ad hoc* basis. In these instances, the invited *ad hoc* reviewer must adhere to Col requirements and have no financial relationships above level IV. [see separate document]

## 3. Process of Revisiting Existing Guideline

- 3.1. Reviewers will meet to discuss the document, with consideration for the following questions:
  - 3.1.1. Are there significant portions of the current document that are outdated due to changes in technology and/or clinical practice?
  - 3.1.2. Are there major shifts in clinical practice or advances in technology that are not reflected in the document?
  - 3.1.3. Does the guideline have significant conflict with other published standards/guidelines?
  - 3.1.4. Are there major research publications or guidelines/standards that were not included?
- 3.2. Work group should reach consensus on these points prior to formulating recommendation

## 4. <u>Recommendation to GC will be made from among the following:</u>

- 4.1. Reaffirm current document with scheduled review in 5 years
- 4.2. Reaffirm current document and revisit at a time sooner than 5 years
  - 4.2.1. Recommendation should specify reasons for early review and suggested time frame
- 4.3. Update document now
  - 4.3.1. Recommendation should identify any specific reasons revision is required, and comment on urgency of revision
  - 4.3.2. Guideline revision could be proposed by any ACNS member; if no member volunteers to lead the proposal, GC may invite members to propose a revision
- 4.4. Retire current document
  - 4.4.1. In the rare case where a document no longer reflects acceptable guidance, and timely revision is either not possible or would not sufficiently remediate the document, a guideline may be retired. (example: technology that has become obsolete)

# 5. Approval of Recommendation

- 5.1. Recommendations will be presented to full GC with vote to approve by majority of those in attendance at meeting
- 5.2. After full GC vote, ACNS ExComm will have final approval of recommendations
- 5.3. If document is approved to Reaffirm, update tag on ACNS website stating date document last reviewed and affirmed 5.3.1. Notice of affirmed guidelines on JCN website as per JCN procedures
- 5.4. If document identified as needing revision, move to pathway for Proposal of New Guidelines [see separate document]
- 5.5. If document to be retired, discuss with Editor-in-Chief of JCN whether an editorial or letter might detail process and reasons behind decision, and next steps within JCN website to retire guideline.

#### Endorsement

- 1. When an organization requests endorsement of an externally-generated position statement or guideline, the ACNS President shall, in consultation with the Guidelines Committee chair, appoint a taskforce to review the document in question and to provide a recommendation to Council.
- 1.1. The taskforce should ideally be chaired by a member of Council or the Guidelines Committee or other member who is both familiar with ACNS guidelines and a subject matter expert.
  - 1.1.1. Other ACNS members with knowledge of the subject matter may be asked to serve on the taskforce.
- 2. If concerns are raised during Council review, a full Council meeting will be called to discuss. In absence of significant concerns, Council can defer to ExComm for final approval.p

### Translation into Languages other than English

- 1. JCN will publish translations of ACNS Guidelines, Consensus Statements and Position Papers after such translations have been approved by ACNS. The general principles noted below should be considered when translating these works.
  - 1.1. Translations will be published as JCN on-line only content. These translations will be citable as JCN papers.
  - 1.2. The original JCN paper should be translated as closely as possible. Each translation will be reviewed by the ACNS to determine accuracy and acceptability.
  - 1.3. Authorship of the original paper will be maintained in the translation.
  - 1.4. The author(s) of the translation should include a brief editorial commentary at the start of the translation about why the translation was done and the need for such a translation. Any commentary about the paper itself should be included here rather than in the translation of the paper.
- 2. Translation Procedures
  - 2.1. Requests to translate an ACNS Guideline into languages other than English shall be directed to the Guidelines Committee.
  - 2.2. The Guidelines Committee chairman shall, in consultation with the committee, President or Executive Committee, identify an ACNS member fluent in the language in question to review the translation provided by the international organization to ensure that the content is not materially changed by the translation.
  - 2.3. Upon confirmation that the integrity of the guideline is preserved by the translation, the requesting organization shall be notified and asked to include with the translation a disclaimer as follows, as well as the citation for the original English-language guideline published in JCN.

Permission for this translation has been obtained from the American Clinical Neurophysiology Society (ACNS) and Wolters Kluwer has approved copyright reuse.

In the present text, we attempt to translate the American Clinical Neurophysiology Society (ACNS) \_\_\_\_ (insert what is being translated) into the \_\_\_\_ (insert language) language with the purpose of enabling its use in a standardized way in \_\_\_\_\_ (insert region or country). We understand the difficulties and limitations inherent to any translation. Some terms defined by ACNS are difficult to translate into \_\_\_ (insert language); others cannot or should not be translated because of the risk of compromising the clarity of the original definition.

We understand that some terms are validated in their original English form. (You may insert an example such as-One of the most significant examples is the old term PLEDs (periodic lateralized epileptiform discharges). In this translation we are choosing to keep some untranslated terms with their acronyms, because the use of the acronym in the original English form facilitates communication between \_\_\_\_\_ (insert region or country) and international centers.

We hope to extend the benefits of this ACNS \_\_ (insert Guideline or Terminology) to neurophysiologists who use the \_\_\_ (insert language) language.

Finally, we emphasize that the use of this terminology in any publication should cite the original article published by ACNS.

The reference for the original article is as follows: (*Insert ACNS publication*)

TRANSLATION: (Insert authors with their institutional affiliation)