

Criteria and Procedures for Submission

and Review of Proposed Changes to the DSM

DSM Steering Committee | Revised November 5, 2019

AMERICAN
PSYCHIATRIC
ASSOCIATION



Criteria for Submission of Proposed Changes

To facilitate the work of the DSM Steering Committee (SC), we require that all proposals for change to DSM-5 be submitted in a standard format (called a “Proposal in Support of Change” or PSC). “Change” is defined as the addition, deletion, or modification of diagnostic categories or criteria.

Six types of proposed changes are anticipated:

Type 1: Changes to an existing diagnostic criteria set.

For Type 1 changes, the PSC would need to provide substantial evidence that the proposed changes would markedly improve at least one of the following:

- **Type 1a.** — Validity of an existing diagnostic criteria set.
- **Type 1b.** — Reliability of a diagnostic criteria set, without an undue reduction in validity;
- **Type 1c.** — Clinical utility of a diagnostic criteria set, without a reduction in validity or reliability
or would substantially reduce:
- **Type 1d.** — Deleterious consequences associated with a diagnostic criteria set, without a reduction in validity

Type 2: Addition of a new diagnostic category or specifier

For Type 2 changes involving a new category, the PSC must provide substantial evidence that the proposed category would accomplish all of the following:

- Meet criteria for a mental disorder (see DSM-5, p. 20);
- Have strong evidence of validity (see Part III, below);
- Be capable of being applied reliably (i.e., at least moderate reliability has been demonstrated [see

Part IV, below]);

- Manifest substantial clinical value (e.g., identify a group of patients now not receiving appropriate clinical attention; facilitate the appropriate use of available treatment[s]);
- Avoid substantial overlap with existing diagnoses, and not be better conceptualized as a subtype of an existing diagnosis; and
- Have a positive benefit/harm ratio (e.g., acceptable false positive rate; low risk of harm due to social or forensic considerations).

For type 2 changes involving the addition of a new specifier or subtype, the PSC should provide substantial evidence that the new specifier/subtype:

- Has strong evidence of validity (e.g., identifies a subgroup of patients with a common biological marker) or clinical utility (e.g., identifies a subgroup of patients that responds to the same treatment),
- Can be applied reliably, and
- Avoids substantial overlap with existing specifiers or subtypes

Type 3: Deletion of an existing diagnostic category or specifier/subtype

For Type 3 changes involving the deletion of an existing category, the PSC must provide substantial evidence that the existing category:

- Has weak evidence of validity, and
- Has minimal utility (e.g., is rarely used in clinical practice or research), or
- Does not meet criteria for a mental disorder or is better conceptualized as a subtype of an existing diagnosis.

For Type 3 changes involving the deletion of an existing specifier or subtype, the evidence required for the PSC will vary depending on the nature of the specifier/subtype. For specifiers/subtypes that are simply descriptive (e.g., alcohol withdrawal, with perceptual disturbances), the PSC should provide

substantial evidence that the specifier/subtype:

- Has minimal utility (e.g., is not useful or is rarely used in clinical practice or research)

For specifiers/subtypes that have predictive or treatment implications, the PSC should provide substantial evidence that the specifier/subtype:

- Has evidence of poor validity, or
- Causes deleterious consequences that would be remedied by deleting the specifier/subtype

Type 4: Corrections and clarifications (including changes aimed at improving the understanding and application of an ambiguous diagnostic criterion, specifier, or text).

For Type 4 changes involving correction or clarification of the wording of a criteria set, specifier, or text, the PSC should provide:

- Clear, common sense evidence that the change is merited, and
- An analysis of the advantages and disadvantages of the proposed change

Type 5: Changes to the Text (not necessitated by changes to diagnostic criteria)

For Type 5 changes involving alterations of the DSM text that are not necessitated by changes to diagnostic criteria, the PSC must provide clear, commonsense evidence (and when available, empirical evidence) that:

- The current text could result in errors in diagnosis, which would be avoided by the proposed change(s); or
- The current text could lead to other harms to patients, which would be avoided by the proposed change(s); or
- The current text reflects a clear and significant error of fact.

Type 6: Additions to Section 3, Conditions for Further Study

- Additions to Sec. 3 can be requested by a proposer or recommended by the SC after reviewing a Type 2 proposal for addition of a new diagnostic category. For Type 6 changes, the PSC should provide evidence that the following criteria are met:

- The proposed disorder is likely to meet criteria for a mental disorder, although current data may be inadequate to make a definitive determination.
- The proposed disorder is not just a manifestation of another disorder (e.g., not just the extreme end of the severity distribution of an existing diagnosis), stress response, or a culturally determined manifestation of a currently included disorder.
- Inclusion of the disorder is likely to have a positive benefit/harm ratio (e.g., acceptable false positive rate).

AND

- Existing evidence of validity or reliability is insufficient to warrant inclusion of the proposed disorder in Section 2 of the DSM. For example, existing data may only include small sample sizes, variable definitions of the proposed disorder, inconsistent study methods, or reliance on a single population, location, or research team.

OR

- The proposed disorder may have substantial clinical value, but additional study is needed to prove clinical utility, including improved clinical outcome.

APA staff in consultation with the chair and vice-chairs of the SC will screen all submitted PSCs. Substantive proposals will be referred to the full SC for further consideration. Proposals for corrections and clarifications (i.e., Type 4 proposals) will be forwarded to a subcommittee of the SC (see Procedures below).

We first describe the components that should be included in every PSC for Type 1 through 3 changes, and then provide specific instructions for proposals according to the type of change proposed (i.e., Types 1 through 5 above). [For Type 4 changes, skip to Specific Guidance below.]

Part I: Reasons for Change

The PSC should state clearly the proposed change, outlining the justification for the change, and stating which one of the types listed above is its main focus. The introduction should also put the proposal into its historical context.

The PSC should include a discussion of possible negative consequences of the proposed change and a consideration of arguments against the change.

Given that it is desirable that proposed changes to DSM-5 reflect a broad consensus of expert opinion, the proposal should include a brief section outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change.

Part II: Magnitude of the Change

The proposer should specify the magnitude of the proposed change, i.e., whether it is best considered a modest change, or a substantial change, using the following guidelines. One important determinant of the magnitude of change is whether it is likely to lead to a change in caseness.

Modest change includes:

- a. Changes to a definition of an existing specifier or subtype that go beyond clarification of an ambiguity of the definition. An example would be changing the number of binges per week that define mild, moderate, severe and extreme binge eating disorder based on new empirical evidence.
- b. Additions to the “examples of presentations” that can be specified using the “other specified” designation.
- c. Changes to diagnostic criteria that are not likely to result in a change in caseness.

Substantial change includes:

- a. Addition of a new diagnosis, specifier, or subtype or the deletion of a diagnosis, specifier, or subtype.
- b. Changes to the DSM-5 criteria that have the potential to result in shifts in caseness from one diagnostic category to another (e.g., a change in the duration of mood symptoms required in the diagnosis of schizoaffective disorder, shifting individuals from Schizoaffective to Schizophrenia)
- c. Addition of a new specifier or subtype to a diagnosis
- d. Changes to the DSM-5 criteria of a well-studied/ well-validated diagnosis that could create significant discontinuities in research or clinical care (e.g., elimination of somatic symptoms from criteria for a Major depressive episode), regardless of the potential for causing shifts in caseness or treatment.

The SC will make an independent determination of the magnitude of the change based on the proposer’s presentation in light of the above parameters.

To determine which of the following sections are relevant to a specific PSC, see “Specific Guidance for Each Type of Proposal” below.

Part III: Validators for the Change

This section should contain a thorough review of the relevant literature and results from any secondary data analyses conducted by the proposers. Proposals for change should, in so far as possible, focus on a single question that evaluates two alternative hypotheses. For Type 1a (criteria set changes to improve validity), the question will typically be: *is the validity of the proposed set of criteria for disorder X superior to the DSM-5 criteria for disorder X?* However, for proposals for new criteria sets (Type 2), two questions will typically need to be addressed: i) does the new disorder have sufficient validity to be included as an official DSM category and ii) is the new disorder sufficiently distinct, in its performance on validators, from other disorders already in the manual to constitute an independent disorder?

For criteria set changes that aim to improve reliability (Type 1b), utility (Type 1c), or reduce deleterious consequences (Type 1d), the question will typically be: *is the validity of the proposed set of criteria for disorder X at least equal to that of the current DSM-5 criteria for disorder X* (which may simply involve a lack of change in caseness between the DSM-5 criteria and the proposed criteria)?

This section should be organized around the following eleven classes of validating criteria. Proposers should note that the SC would prefer to see evidence for validity from a diversity of populations, especially for substantial changes. In addition, the SC recognizes that for many PSCs, data may not be available for many of these categories.

I. Antecedent Validators

- A. *Familial aggregation and/or co-aggregation (i.e., family, twin or adoption studies)
- B. Socio-Demographic and Cultural Factors
- C. Environmental Risk Factors
- D. Prior Psychiatric History

II. Concurrent Validators

- A. Cognitive, emotional, temperament, and personality correlates (unrelated to the diagnostic criteria).
- B. *Biological Markers, e.g., molecular genetics, neural substrates
- C. Patterns of Comorbidity
- D. *Degree or nature of functional impairment

III. Predictive Validators

- A. *Diagnostic Stability
- B. *Course of Illness
- C. *Response to Treatment

Asterisks denote high priority validators that will generally be seen as providing stronger evidence than the other validators listed above. The PSC should contain a summary table for each relevant validator class (i.e., each validator for which data exist). In this table, each study would be represented by a row, with columns reflecting the lead author, year of publication, sample size, methods, and a brief summary of the relevant results. Proposers are encouraged to include a qualitative judgment of the overall methodological strength of each study (e.g., on a 1-5 scale) as indicated by, e.g., quality of diagnostic assessments and validating measures, size and representativeness of the sample, and rigor of the statistical analyses.

It is desirable to have a final summary table in which rows represent the relevant validators. The table should summarize the degree to which data from each validator class support the proposed change (again on a 1-5 scale).

Because of the inclusion of these tables, the text can be brief, focusing first on summarizing the overall nature and strength of the data and commenting on controversial issues, contradictory data, and/or the importance of particular studies or methods.

Part IV: Reliability

Information should be summarized in tabular form about the comparative reliability of the proposed criteria and, if relevant, the reliability of the DSM-5 criteria that they seek to replace. We recommend a table with a line for each study that lists the sample size, the reliability (preferably calculated by the kappa coefficient or one of several related chance-corrected statistics), the type of reliability

assessed (e.g., inter-rater, inter-interviewer, test-retest), the nature of the sample (e.g., clinical versus epidemiological) and prior training of the interviewers. If possible, improved reliability should be shown across different populations. The proposers should present data showing that the proposed criteria improve reliability while identifying largely the same cases as the original DSM-5 criteria, unless an improvement in validity is also being claimed.

Part V: Clinical Utility

Proposers should summarize available information about the clinical utility of their proposed criteria compared to the current DSM-5 criteria. For example, if the proposal shortens the criteria set, information should be provided here about the degree to which caseness would be altered by the new, briefer criteria. That is, the argument that shortening a criteria set does not lead to a loss of validity could be accomplished by showing a very high rate of agreement between case definition by the newer, shorter and the older, longer DSM-5 criteria. Note, to be convincing, this should be shown in several populations differing by gender, age, ethnicity, etc.

Although the types of empirical studies that would be helpful to establish an improvement in clinical utility are less well established than for validity and reliability, a 2004 paper by First and colleagues (*Am J Psychiatry* 2004; 161:946-954), developed by an ad hoc subcommittee of the American Psychiatric Association's Committee on Psychiatric Diagnosis and Assessment, provides some guidance. Parameters of clinical utility that could be measured include whether proposed changes improve user acceptability, clinicians' ability to apply the diagnostic criteria accurately, clinicians' adherence to practice guidelines, and ultimately clinical outcomes.

Proposals that would improve the clinician's ability to select the best treatment or determine prognosis, while certainly improving the clinical utility of the DSM-5, are best considered to be proposals to improve validity and are better included under part III above.

Part VI: Deleterious Consequences

Proposers should summarize available information about the potential deleterious consequences of the current DSM-5 criteria and, if they exist, how the proposed criteria change will reduce or

eliminate them. For example, if over-diagnosis is being claimed, empirical evidence will need to be presented demonstrating false positive diagnoses utilizing DSM-5 criteria. The proposers should also present data showing the degree to which their proposed criteria reduce the deleterious consequences of the criteria. Proposals for new diagnostic categories should comment on potential deleterious consequences of their adoption.

Specific Guidance for Each Type of Proposal

Specific types of proposals to change criteria sets are based on the primary area that is expected to be improved by the proposed changes. We recognize that many proposals will be “hybrids,” i.e., the proposers will claim positive effects consistent with more than one type of proposal.

Type 1a Proposals (changes to improve validity). Part III will be the major focus of such proposals but parts I and II should be completed carefully. Although such proposals may have limited information on changes in reliability or utility, some comments should be made for parts IV and V. A brief comment should also be made with respect to part VI, i.e., if there are any deleterious consequences of the DSM-5 criteria, whether these would be changed by the revised criteria, and whether the revision raises the possibility of new deleterious consequences.

Since these are likely to be the most common types of proposals, we provide some additional comments here.

1. Even requests for modest changes should have at least some support from the validators listed above.
2. Substantial changes should generally have broad support from several validator classes and particularly from at least one high priority validator. For most substantial changes, we would expect support from several high priority validators.
3. Substantial changes should rarely if ever be based solely on reports from a single researcher or research team.
4. Substantial changes should generally have consistent support across validators. In particular, we would not generally expect to recommend adoption of substantial changes if a significant

proportion of the literature contained evidence that contradicted the evidence presented in support of the change.

Type 1b Proposals (changes to improve reliability)

The major focus of such proposals will be on part IV but all other parts should be completed. Part III will typically be much briefer than for type 1a (validity) proposals. Here the goal is to provide information that the criteria changes that produce better reliability do not result in a decline in validity. The larger the changes to criteria in these proposals, the stronger the evidence will need to be for improved reliability without a change in validity.

Type 1c Proposals (changes to improve utility).

Here the major focus will be on part V. Parts III and IV will typically be briefer than those seen in type 1a (validity) and type 1b (reliability) proposals, respectively. Part VI should also be commented upon briefly. The major focus of such proposals will be to demonstrate that the changes in criteria that improve clinical utility do not result in decreased validity and/or reliability. The larger the changes to criteria in these proposals, the stronger the evidence will need to be for improved utility and no change in validity.

Type 1d Proposals (changes to reduce deleterious consequences)

During the DSM-5 process, critics raised concerns that several of the changes were likely to lead to individuals without mental disorders being inappropriately labeled as having a disorder. For example, some critics cautioned that formulating somatic symptom disorder (SSD) in terms of somatic complaints combined with excessive thoughts, feelings, or behaviors related to the somatic complaints was likely to label individuals with a medical illness as having a somatic symptom disorder. Any proposal to change somatic symptom disorder on these grounds would require empirical evidence that medically ill but psychiatrically well individuals are in fact receiving the SSD diagnosis and that the proposed change would correct this problem. All other parts need to be commented on. In particular, there needs to be reasonable evidence that these changes will not be accompanied by a reduction in diagnostic validity. The larger the changes to criteria in these proposals, the stronger the evidence will need to be for a reduction in deleterious consequences and no change in reliability.

In the appendix to this document, the SC provides examples of what it considers to be high quality

reviews of validators as well as table templates that should be used by proposers to organize the data for their PSC.

Type 2 Proposals (addition of a new category or specifier): Part I (reasons for change) and Parts III (validity), IV (reliability), and V (utility) should be the focus of these proposals. (Part II need not be completed because by definition, Type 2 proposals are considered to be “substantial.”) There should be strong evidence of validity, evidence of at least moderate reliability, and there should be some clinical utility related to the addition of the new category (e.g., identifying a group of patients that are likely to respond to a particular intervention). In addition, Part I should include a discussion of why the proposed condition meets the definition of mental disorder and a discussion of the likely benefit/harm ratio.

Type 3 Proposals (deletion of an existing category, subtype or specifier): The major focus of the proposal should be Part I (reasons for change) and Parts III (validity), V (utility), and possibly VI (deleterious consequences). Part III (validity) should focus on evidence regarding lack of validity or that it is better conceptualized as a subtype of an existing diagnosis. Part V should offer evidence of minimal utility. If relevant, part VI would focus on evidence that the current use of the category, subtype or specifier in DSM-5 has deleterious consequences that would be eliminated by its deletion.

Type 4 Proposals (corrections and clarifications not requiring empirical data for justification): These proposals should demonstrate:

1. Lack of clarity or ambiguity in the wording of a criteria set or text,
2. Inconsistencies or contradictions within the text or criteria, or
3. Errors of omission or inadvertent inclusion, and
4. The change is not likely to produce a substantial change in caseness

Proposers in this category need not complete the full PSC and do not require empirical evidence per se, but should provide clear, common sense evidence that the change is merited, and should indicate how the proposed change rectifies the problem in the criteria and/or text. They should also note any disadvantages of the proposed change.

Type 5 proposals (changes to the text not necessitated by changes in diagnostic criteria):

The DSM is not intended as a comprehensive textbook of psychiatry. The text is designed to aid in applying the diagnostic criteria, not to provide a complete summary of what is known about each disorder. Hence, until a comprehensive text revision is undertaken, changes to the text other than those necessitated by alterations in diagnostic criteria will be limited to emendations designed to avoid errors in diagnosis or other harms to patients, or that reflect clear and significant errors of fact.

Proposers need not complete the full PSC.

- If the proposal is based on the likelihood that the text will result in errors in diagnosis, a clear statement of why that is the case and how the proposed change would avoid future errors should be submitted; empirical evidence that such errors occur and, if available, how the proposed change would avoid them is desirable.
- If the proposal is based on the likelihood that the current text could lead to other harms to patients, a clear statement of why that is the case and how the proposed change would avoid future harms should be submitted; empirical evidence that such harms occur and, if available, how the proposed change would avoid them is desirable.
- If the proposal is based on the current text reflecting a putative error of fact, a clear statement of the error and why it is significant, and convincing empirical data demonstrating the nature of the error should be submitted. When the issue in question is in dispute, a fair summary should be provided of empirical data supporting each side of the dispute.

Type 6 proposals (additions to Sec. 3, Conditions for Further Study): See instructions for Type 2 proposals.

Procedures for Submission and Review of Proposed Changes

Initial Receipt and Review of Proposals: Proposals for changes to DSM submitted through the web portal will be screened by the APA Research staff assigned to support the Steering Committee. The screening will identify proposals not appropriate for forwarding to the Steering Committee, including incomplete submissions, which will be referred back to the proposers for completion, and submissions that represent inappropriate use of the submission

process. If in doubt as to whether a proposal should be forwarded to the Steering Committee, the assigned APA staff will consult with the chair and vice-chairs of the Steering Committee.

Type 1, 2, 3, 5 and 6 Proposals

All complete, substantive proposals (i.e., Types 1, 2, 3 and 6) will then be forwarded to the Steering Committee for review to determine whether the proposal should be referred to the appropriate Review Committee for further consideration. The Steering Committee has the option of asking persons whom it identifies as experts in relevant areas to comment on it. Two members of the Steering Committee will be assigned as a primary and a secondary reviewer to present and critique the proposal at the beginning of the Steering Committee's discussion. Based on its own assessment and any comments from outside experts, the Steering Committee will determine whether the proposal should be referred to the appropriate Review Committee. To make a decision for referral, the Steering Committee must determine that the evidence in support of the proposal appears likely to meet the criteria for approval. Proposers will receive notification as to whether their proposal has been forwarded to a Review Committee. In the case of proposals that are not forwarded, the Steering Committee will provide the proposer(s) with a brief explanation of the rationale for its decision.

Type 4 Proposals

Proposals for clarifications and corrections of existing DSM-5 criteria and text (Type 4 proposals) will be referred to a subcommittee of the Steering Committee. The subcommittee will review the proposal to determine whether it is appropriate to consider it as a Type 4 proposal. If the subcommittee concludes that it is not, it will refer the proposal back to the Steering Committee, which will communicate with the proposers. If the subcommittee concludes that the proposal can appropriately be considered as a Type 4 proposal, it will consider the proposal on its merits, if necessary consult with experts in the relevant area, and determine whether to recommend approval to the Steering Committee. If the subcommittee recommends approval, the Steering Committee will follow the process described in the section on "Review of Proposals Submitted by a Review Committee to the Steering Committee" below.

Review and Modification of Proposals by the Review Committee: On receipt of a proposal from the Steering Committee, the Review Committee will consider the evidence in support of the proposed change. In doing so, the Review Committee will undertake whatever additional investigation is required (e.g., review of additional literature not cited in the proposal, consultation with experts in relevant areas) and summarize their findings. This may involve revision of the tables of validators and/or a narrative summary. The Review Committee may suggest revisions to the original proposal, as appropriate. If the Review Committee believes clarification or additional information is needed from the proposers, it will notify the chair of the Steering Committee, who will communicate with the proposers. Should the Review Committee conclude that the proposal does not meet criteria for revision, it will report that conclusion to the Steering Committee, which may accept it or propose grounds for reconsideration by the Review Committee. Otherwise, the Review Committee will forward the proposal to the Steering Committee, including its suggested revisions, utilizing a standard format and scoring system created by the Steering Committee. The Steering Committee will establish a timeline for the Review Committee's tasks reflecting the complexity and extent of the proposed revision, and will require regular progress reports to ensure timely completion.

Review of Proposals Submitted by a Review Committee to the Steering Committee: On receipt of a proposal or revised proposal from a Review Committee, the Steering Committee has the option of asking for comment from additional persons whom it identifies as experts in the area. After discussion of the proposal, taking such expert opinion into account, the Steering Committee will decide whether the proposal is suitable to be posted for public comment. **To decide to post for public comment, the Steering Committee must determine that there is considerable evidence in support of the proposal, and that public comment is therefore warranted.** Alternatively, the Steering Committee may refer the proposal back to the Review Committee for further modification, with specific guidance for the Review Committee as to the changes that are requested and the basis for them, or it may reject the proposal.

When a determination is made to post a proposal for public comment, appropriate and timely notice will be given (e.g., in *Psychiatric News*' email version), and organizations likely to have a

specific interest in the proposal will be notified. The proposal will remain online and open for comment for a period of not less than 30 days. After the public comments are collated and reviewed, they will be summarized and shared with the relevant Review Committee for additional deliberation, if necessary. If the comments are largely supportive of the proposal, the Steering Committee will make a final determination regarding whether to recommend approval of the proposal. If the Steering Committee recommends approval, it will forward the proposal, along with an explanation of the recommendation for approval and a summary of the public comments, for review by the Board of Trustees. **To decide to forward a proposal to the Board, the Steering Committee must determine**

that the proposal has met the criteria for approval. Alternatively, **to reject a proposal the Steering Committee must determine that the proposal has not met the criteria for approval.** In the latter case, notification of the determination with a brief explanation will be forwarded to the proposer(s) and to the Review Committee.

Development of Text after Approval by the Board of Trustees: If a proposal is approved by the Board of Trustees, the Review Committee that considered the proposal will be asked to develop whatever text changes are needed in the DSM to reflect the approved change in a criteria set. The Steering Committee will review and approve those changes prior to forwarding them for inclusion in an updated version of the DSM.