GUIDE TO SUBMITTING PROPOSALS FOR CHANGES TO DSM-5

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Division	Division of Research
Document	Standard Operating Procedure (SOP): DSM Proposal Submission
Effective from:	February 2021

Article I. Before you start the submission

- a) Know the types of proposals that can be submitted and review the document providing specific guidance for each type of proposal
 - a. <u>Type 1</u>: Proposals for making changes to an existing diagnostic criteria set
 - i. <u>Type 1A</u>: Proposals for changes to an existing diagnostic criteria set that would markedly improve its validity
 - ii. <u>Type 1B</u>: Proposals for changes to an existing diagnostic criteria set that would markedly improve reliability without an undue reduction in validity
 - iii. <u>Type 1C:</u> Proposals for changes to an existing diagnostic criteria set that would markedly improve clinical utility without an undue reduction in validity or reliability
 - iv. <u>Type 1D</u>: Proposals for changes to an existing diagnostic criteria set that would substantially reduce deleterious consequences associated with the criteria set without a reduction in validity
 - b. <u>Type 2:</u> Proposals for addition of a new diagnostic category or specifier
 - c. <u>Type 3</u>: Proposals for deletion of an existing diagnostic category or specifier/subtype
 - d. <u>Type 4</u>: Proposals for corrections and clarifications (including changes to improve the understanding and application of an ambiguous diagnostic criterion, specifier, or text)
 - e. <u>Type 5</u>: Proposals for changes to the text (not necessitated by changes to diagnostic criteria)
 - f. <u>Type 6</u>: Proposals for additions to Section 3, Conditions for Further Study
 - g. <u>Type 7</u>: Proposals for additions to Other Conditions that May Be a Focus of Clinical Attention
- b) Review the <u>checklist</u> to understand the types of documents required for specific proposals
- c) Make sure you have the necessary technology tools:
 - i. Ensure that you have a PDF reader on your computer to submit a proposal through this online portal
 - ii. Turn off the pop-up blocker in your web browser

Article II. Starting the submission

- a) Open the submission portal at the <u>APA website</u>
- b) Complete and submit the <u>Confidentiality and Copyright Agreement Disclosure</u> <u>form</u>.
- c) Select the type(s) of change(s) you are proposing by checking the appropriate box(es)

Article III. Type 1 Proposals: Changes to an existing diagnostic criteria set

- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal. Also, add the diagnostic category or name of the disorder that you are proposing to change.
- b) Describe the change you are proposing in a brief paragraph
- c) Provide a reason for the proposed change.
 - (i) Include a clear summary statement of the rationale for the proposed change, outlining the justification for the change.
 - (ii) Include the historical context for your proposal.
 - (iii) Include a discussion of possible negative consequences of the proposed change and consideration of arguments against the change.
 - (iv) Include a brief section in your proposal outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change.
- d) Specify the magnitude of the proposed change, using the definitions provided below, and include a brief rationale for your choice. One important determinant of the magnitude of change is whether it is likely to lead to a change in caseness (i.e., whether an individual will be identified as having the disorder of interest).
 - (i) Indicate the type of change (Modest or Substantial) you are proposing and provide the rationale for the decision in the accompanying text boxes.
 - (ii) Modest changes include:
 - 1) Changes to a definition of an existing specifier or subtype that go beyond clarification of ambiguity of the definition
 - i. 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.
 - 2) Other changes to diagnostic criteria that are not likely to result in a change in caseness
 - (iii) Substantial changes include:

- 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 having a diagnosis of Schizoaffective Disorder to having a diagnosis of Schizophrenia)
- 2) 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.
- e) Provide a summary explanation of data on validators. Include a thorough review of the relevant literature and results from any unpublished secondary data analyses in your proposal and a brief summary. In so far as possible, focus on a single question that evaluates two alternative hypotheses. Attach summary tables as requested.
 - (i) 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?
 - (ii) 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)?
 - (iii) Organize this section around the following eleven classes of validating criteria. Note that reviewers would prefer to see evidence for validity from diverse populations, especially for substantial changes. (It is recognized that, for many proposals, data may not be available for many of these categories.) Asterisks denote high priority validators that will generally be seen as providing stronger evidence than the other validators listed above.
 - 1) Antecedent Validators
 - *Familial aggregation and/or co-aggregation (i.e., family, twin, or adoption studies)

- Socio-Demographic and Cultural Factors
- Environmental Risk Factors
- Prior Psychiatric History
- 2) Concurrent Validators
 - Cognitive, emotional, temperament, and personality correlates (unrelated to the diagnostic criteria).
 - *Biological Markers, e.g., molecular genetics, neural substrates
 - Patterns of Comorbidity
 - *Degree or nature of the functional impairment
- 3) Predictive Validators
 - *Diagnostic Stability
 - *Course of Illness
 - *Response to Treatment
- (iv) Attach a summary table to your full proposal for each relevant validator class (i.e., each validator for which data exist). Each study should 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.
- (v) You 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.
- (vi) 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).
- f) Provide a summary of data on reliability.
 - (i) Information should be summarized in a tabular form about the comparative reliability of the proposed criteria and, if relevant, the reliability of the DSM-5 criteria that you seek to replace.

- (ii) A table with a line for each study that lists the sample size, the reliability (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 is recommended.
- (iii) If possible, improved reliability should be shown across different populations. Data should be presented 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.
- g) Provide a summary explanation of data on clinical utility:
 - (i) Summarize available information about the clinical utility of the proposed criteria compared to the current DSM-5 criteria in your proposal and in the given text box. For example, if the proposal shortens the criteria set, the information should be provided here about the degree to which caseness would not be altered by the new, briefer criteria. That is, demonstrating that shortening the 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, when possible this should be shown in several different populations differing by gender, age, ethnicity, etc.
 - (ii) 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 (<u>Am J Psychiatry 2004; 161:946–954</u>), developed by an ad hoc subcommittee of the American Psychiatric Association's Committee on Psychiatric Diagnosis and Assessment, provides some guidance.
 - (iii) 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.

- (iv) 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 (Type 1A), discussed below.
- h) Provide a summary of deleterious consequences.
 - (i) Summarize the available information about the potentially 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.
 - (ii) Include data showing the degree to which the proposed criteria reduce the deleterious consequences of the criteria. Proposals for new diagnostic categories should comment on the potentially deleterious consequences of their adoption.
- i) Submit the proposal: Attach the full proposal and appendices. Note that only PDF documents can be uploaded.

Specific Guidance for Type 1 Subtype Proposals:

a) Type 1A: Proposal for Changes to Improve Validity

For Type 1A proposals, Part III of the submission portal 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, some additional comments are provided here.

- Even requests for modest changes should have at least some support from the validators listed under Part III of the online submission portal – Validators for the Change.
- (ii) Substantial changes should generally have broad support from several validator classes and particularly from at least one high priority validator. For most substantial changes, support from several high priority validators should be provided.
- (iii) Substantial changes should rarely, if ever, be based solely on reports from a single researcher or research team.
- (iv) Substantial changes should generally have consistent support across validators. In particular, proposals for substantial changes would not generally be accepted if a significant proportion of the literature contained evidence that contradicted the evidence presented in support of the change.
- b) Type 1B: Proposals for Changes to an Existing Criteria Set to Improve Reliability For Type 1B proposals, Part IV of the submission portal will be the major focus of your proposal, 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.

- c) Type 1C: Proposal for Changes to Improve Clinical Utility For Type 1C Proposals, the major focus will be on part V of the submission portal. 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.
- d) Type 1D: Proposal for Changes to Reduce Deleterious Consequences For Type 1D Proposals, part IV of the submission portal will be the primary focus of your proposal. 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 portions of the submission portal need to be completed. In particular, reasonable evidence must be provided 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 validity and reliability.

Article IV. Type 2 Proposals: Addition of a new diagnostic category or specifier

For Type 2 changes involving a new diagnostic category, you will be asked to provide substantial evidence that the proposed category would accomplish all of the following:

- (i) Meet criteria for a mental disorder
- (ii) Have strong evidence of validity
- (iii) Be capable of being applied reliably
- (iv) 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])
- (v) Avoid substantial overlap with existing diagnoses, and not be better conceptualized as a subtype of an existing diagnosis, and
- (vi) 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, you will need to provide substantial evidence that the new specifier/subtype:

- (i) Has strong evidence of validity or clinical utility
- (ii) Can be applied reliably
- (iii) Avoids substantial overlap with existing specifiers or subtypes
- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal
- b) Describe the change you are proposing in a brief paragraph
- c) Provide a reason for the proposed change.
 - (i) Include a clear summary statement of the rationale for the proposed change, outlining the justification for the change
 - (ii) Include the historical context for your proposal
 - (iii) Include a discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (iv) Include a brief section in your proposal outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change

- d) Specify the magnitude of the proposed change and include a brief rationale for your choice. Addition of a new diagnostic category or a specifier is considered a substantial change.
- e) Provide a summary explanation of data on validators. Include a thorough review of the relevant literature and results from any unpublished secondary data analyses in your proposal and a brief summary in the given text box. Insofar as possible, focus on a single question that evaluates two alternative hypotheses. Attach summary tables as requested.
 - (i) For Type 2 proposals, two questions will typically need to be addressed:
 - 1) Does the new disorder have sufficient validity to be included as an official DSM category?
 - 2) Is the new disorder sufficiently distinct in its performance on validators from other disorders already in the manual to constitute an independent disorder?
 - (ii) Organize this section around the following eleven classes of validating criteria. Note that reviewers would prefer to see evidence for validity from diverse populations, especially for substantial changes. (It is recognized that, for many proposals, data may not be available for many of these categories.) Asterisks denote high priority validators that will generally be seen as providing stronger evidence than the other validators listed above.
 - 1) Antecedent Validators
 - *Familial aggregation and/or co-aggregation (i.e., family, twin, or adoption studies)
 - Socio-Demographic and Cultural Factors
 - Environmental Risk Factors
 - Prior Psychiatric History
 - 2) Concurrent Validators
 - Cognitive, emotional, temperament, and personality correlates (unrelated to the diagnostic criteria).
 - *Biological Markers, e.g., molecular genetics, neural substrates
 - Patterns of Comorbidity
 - *Degree or nature of the functional impairment

- 3) Predictive Validators
 - *Diagnostic Stability
 - *Course of Illness
 - *Response to Treatment
- (iii) Attach a summary table to your full proposal for each relevant validator class (i.e., each validator for which data exist). Each study should 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.
- (iv) You 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.
- (v) 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).
- f) Provide a summary of data on reliability.
 - (i) Information should be summarized in a tabular form about the comparative reliability of the proposed criteria and, if relevant, the reliability of the DSM-5 criteria that you seek to replace.
 - (ii) A table with a line for each study that lists the sample size, the reliability (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 is recommended.
 - (iii) If possible, improved reliability should be shown across different populations. Data should be presented 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.
- g) Provide a summary explanation of data on clinical utility:

- (i) Summarize available information about the clinical utility of the proposed criteria in your proposal and in the text box.
- (ii) 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 (<u>Am J Psychiatry 2004; 161:946–954</u>), developed by an ad hoc subcommittee of the American Psychiatric Association's Committee on Psychiatric Diagnosis and Assessment, provides some guidance.
- (iii) 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.
- (iv) Improvements in the clinician's ability to select the best treatment or determine prognosis should be noted as part of the data on validators discussed above.
- h) Provide a summary of deleterious consequences.
 - (i) Summarize the available information about the potentially deleterious consequences of the absence of current DSM-5 criteria for the proposed disorder, and how they will be ameliorated by the new criteria set.
 - (ii) Proposals for new diagnostic categories should comment on the potentially deleterious consequences of their adoption.
- i) Submit the proposal: Attach the full proposal and appendices. Note that only PDF documents can be uploaded.

Article V. Type 3 Proposals: Deletion of an existing diagnostic category or specifier/subtype

For Type 3 changes involving the deletion of an existing category, you will be asked to provide substantial evidence that the existing category:

- (i) Has weak evidence of validity; and
- (ii) Has minimal utility (e.g., is rarely used in clinical practice or research); or
- (iii) Does not meet the 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 will vary depending on the nature of the specifier/subtype. For specifiers/subtypes that are simply descriptive (e.g., alcohol withdrawal, with perceptual disturbances), you should provide substantial evidence that the specifier/subtype:

(i) 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, you should provide substantial evidence that the specifier/subtype:

- (i) Has evidence of poor validity, or
- (ii) Causes deleterious consequences that would be remedied by deleting the specifier/subtype
- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal
- b) Describe the change you are proposing in a brief paragraph
- c) Provide a reason for the proposed change.
 - (i) Include a clear summary statement of the rationale for the proposed change, outlining the justification for the change.
 - (ii) Include the historical context for your proposal.
 - (iii) Include a discussion of possible negative consequences of the proposed change and consideration of arguments against the change.

- (iv) Include a brief section in your proposal outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change.
- d) Specify the magnitude of the proposed change. Deletion of an existing diagnostic category or specifier/subtype is considered a substantial change.
- e) Provide a summary explanation of data on validators, demonstrating the weak evidence for validity of the disorder. Include a thorough review of the relevant literature and results from any unpublished secondary data analyses in your proposal and a brief summary in the given text box. Insofar as possible, focus on a single question that evaluates two alternative hypotheses. Attach summary tables as requested.
 - (i) Organize this section around the following eleven classes of validating criteria. Note that reviewers would prefer to see lack of evidence for validity from diverse populations, especially for substantial changes. (It is recognized that, for many proposals, data may not be available for many of these categories.) Asterisks denote high priority validators that will generally be seen as providing stronger evidence than the other validators listed above.
 - 1) Antecedent Validators
 - *Familial aggregation and/or co-aggregation (i.e., family, twin, or adoption studies)
 - Socio-Demographic and Cultural Factors
 - Environmental Risk Factors
 - Prior Psychiatric History
 - 2) Concurrent Validators
 - Cognitive, emotional, temperament, and personality correlates (unrelated to the diagnostic criteria).
 - *Biological Markers, e.g., molecular genetics, neural substrates
 - Patterns of Comorbidity
 - *Degree or nature of the functional impairment
 - 3) Predictive Validators
 - *Diagnostic Stability
 - *Course of Illness
 - *Response to Treatment

- (ii) Attach a summary table to your full proposal (which you will be asked to submit at the end of this survey) for each relevant validator class (i.e., each validator for which data exist). Each study should 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.
- (iii) You 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
- (iv) 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).
- f) Provide a summary of data on reliability.
 - (i) Information should be summarized in a tabular form, if relevant to the proposal, about the reliability of the DSM-5 criteria that you seek to delete.
 - (ii) A table with a line for each study that lists the sample size, the reliability (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 is recommended.
 - (iii) If possible, data on poor reliability should be shown across different populations.
- g) Provide a summary explanation of data on clinical utility:
 - (i) Summarize available information about the minimal clinical utility of the criteria set proposed for deletion.

- (ii) Although the types of empirical studies that are helpful in assessing clinical utility are less well established than for validity and reliability, a 2004 paper by First and colleagues (<u>Am J Psychiatry</u> 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.
- (iii) Parameters of clinical utility that could be measured include user acceptability, clinicians' ability to apply the diagnostic criteria accurately, clinicians' adherence to practice guidelines, and ultimately clinical outcomes.
- h) Provide a summary of deleterious consequences.
 - (i) Summarize the available information about the potentially deleterious consequences of the current DSM-5 criteria. For example, if over-diagnosis is being claimed, empirical evidence will need to be presented, demonstrating false-positive diagnoses utilizing DSM-5 criteria.
 - (ii) Proposals for deletion of a diagnostic category should comment on the potentially deleterious consequences of the change.
- i) Submit the proposal: Attach the full proposal and appendices. Note that only PDF documents can be uploaded

Article VI. Type 4 Proposals: Corrections and Clarifications

Examples of Type 4 changes include proposals that aim to correct:

- (i) Ambiguity or lack of clarity in the wording of a criteria set or text or
- (ii) Inconsistencies or contradictions within the text or criteria (for example, the descriptive text conflicts with the criteria for a disorder), or
- (iii) Errors of omission or inadvertent inclusion (for example, an inadvertent omission of a disorder in the "not better explained by" list as part of the exclusion criteria for a diagnosis)

For your proposal to be considered a "Type 4 Proposal for Change," you will also need to provide evidence that the change is not likely to produce a substantial change in caseness (i.e., whether an individual will be identified as having the disorder of interest).

- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal. And indicate the diagnostic category or name of disorder for which you are proposing a correction or clarification
- b) Select the type of correction or clarification your proposal addresses from the following options:
 - (i) Ambiguity or lack of clarity in the wording of criteria set or text, or
 - (ii) Inconsistencies or contradictions within the text or criteria (for example, the descriptive text conflicts with the criteria for a disorder)
 - (iii) Errors of omission or inadvertent inclusion (for example, an inadvertent omission of a disorder in the "not better explained by" list as part of the exclusion criteria for a diagnosis)
- c) Describe the correction or clarification that you are proposing, indicate the relevant DSM-5 page number to which it applies, or referencing the online version, the category and title under which it appears.
- d) Provide clear evidence that the proposed change is not likely to produce a substantial change in caseness (i.e., whether or not an individual will be identified as having the disorder of interest).
- e) Give a brief analysis of the advantages and disadvantages of the proposed correction or clarification.
- f) Close the proposal by pressing the "Submit" button

Article VII. Type 5 Proposals: 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, you will be asked to provide clear, commonsense evidence (and when available, empirical evidence) that:

- (i) The current text could result in errors in diagnosis, which would be avoided by the proposed change(s); or
- (ii) The current text could lead to other harms to patients, which would be avoided by the proposed change(s); or
- (iii) The current text reflects a clear and significant error of fact.
- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal. And, select the diagnostic category or name of disorder for which you are proposing a textual change
- b) Select the type of text changes your proposal addresses from the list below:
 - (i) The current text could result in errors in diagnosis, which would be avoided by the proposed change(s)
 - (ii) The current text could lead to other harms to patients, which would be avoided by the proposed change(s)
 - (iii) The current text reflects a clear and significant error of fact
- c) Describe the text change that you are proposing, indicate the relevant DSM-5 page number(s) to which it applies, or referencing the online version, the category and title under which it appears.
- d) If the proposal is based on the likelihood that the text will result in errors in diagnosis, please provide:
 - (i) A clear statement of why that is the case and how the proposed change would avoid future errors
 - (ii) Empirical evidence that such errors occur and, if available, how the proposed change would avoid them
- e) If the proposal is based on the likelihood that the current text could lead to other harms to patients, please provide:
 - (i) A clear statement of why that is the case and how the proposed change would avoid future harm
 - (ii) Empirical evidence that such harms occur and, if available, how the proposed change would avoid them

- f) If the proposal is based on the current text reflecting a putative error of fact, please provide:
 - (i) A clear statement of the error and why it is significant

(ii) Convincing empirical data demonstrating the nature of the error Note: When the issue in question is in dispute, a fair summary should be provided of empirical data supporting each side of the dispute.

g) Complete the proposal by clicking the "Submit" button.

Article VIII. Type 6 Proposals: Additions to Section 3, Conditions for Further Study

For Type 6 changes involving adding a new condition for further study in Section 3, you will be asked to provide substantial evidence that the proposed category:

- (i) Meets criteria for a mental disorder, although current data may be inadequate to make a definitive determination.
- (ii) 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.
- (iii) Is likely to have a positive benefit/harm ratio (e.g., an acceptable false-positive rate).

And that

- (iv) 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
- (v) The proposed disorder may have substantial clinical value, but additional study is needed to prove clinical utility, including improved clinical outcomes.
- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal
- b) Describe the addition you are proposing in a brief paragraph
- c) Provide a reason for the proposed addition.
 - Include a clear summary statement of the rationale for the proposed new Section 3 category, outlining the justification for the addition.
 - (ii) Include the historical context for your proposal.
 - (iii) Include a discussion of possible negative consequences of the proposed addition and consideration of arguments against the addition.

- (iv) Include a brief section in your proposal outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed category.
- d) Specify the magnitude of the proposed change. Addition of a new condition is considered a substantial change.
- e) Provide a summary explanation of data on validators. Include a thorough review of the relevant literature and results from any unpublished secondary data analyses in your proposal and a brief summary in the given text box. Insofar as possible, focus on a single question that evaluates two alternative hypotheses. Attach summary tables as requested.
 - (i) For type 6 proposals, two questions will typically need to be addressed:
 - Does the new disorder have some evidence of validity, even if insufficient to be included as an official DSM category in Section 2?
 - 2) Is the new disorder sufficiently distinct, in its performance on validators, from other disorders already in the manual to constitute an independent disorder?
 - (ii) Organize this section around the following eleven classes of validating criteria. Note that reviewers would prefer to see evidence for validity from a diversity of populations, especially for substantial changes. (It is recognized that, for many proposals, data may not be available for many of these categories.) Asterisks denote high priority validators that will generally be seen as providing stronger evidence than the other validators listed above.
 - 1) Antecedent Validators
 - *Familial aggregation and/or co-aggregation (i.e., family, twin, or adoption studies)
 - Socio-Demographic and Cultural Factors
 - Environmental Risk Factors
 - Prior Psychiatric History
 - 2) Concurrent Validators
 - Cognitive, emotional, temperament, and personality correlates (unrelated to the diagnostic criteria).

- *Biological Markers, e.g., molecular genetics, neural substrates
- Patterns of Comorbidity
- *Degree or nature of the functional impairment
- 3) Predictive Validators
 - *Diagnostic Stability
 - *Course of Illness
 - *Response to Treatment
- (iii) Attach a summary table to your full proposal (which you will be asked to submit at the end of this survey) for each relevant validator class (i.e., each validator for which data exist). In this table, each study should 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.
- (iv) You 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.
- (v) 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).
- f) Provide a summary of data, if available, on reliability.
 - (i) Information should be summarized in a tabular form about the reliability of the proposed criteria.
 - (ii) A table with a line for each study that lists the sample size, the reliability (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 is recommended.
 - (iii) If possible, data on reliability should be shown across different populations.
- g) Provide a summary explanation of data, if available, on clinical utility:

- (i) Summarize available information about the clinical utility of the proposed criteria. If possible, data should be presented for several populations differing by gender, age, ethnicity, etc.
- (ii) Although the types of empirical studies that would be helpful to establish clinical utility are less well established than for validity and reliability, a 2004 paper by First and colleagues (<u>Am J</u> <u>Psychiatry 2004; 161:946–954</u>), developed by an ad hoc subcommittee of the American Psychiatric Association's Committee on Psychiatric Diagnosis and Assessment, provides some guidance.
- (iii) Parameters of clinical utility that could be measured include user acceptability, clinicians' ability to apply the diagnostic criteria accurately, clinicians' adherence to practice guidelines, and ultimately clinical outcomes.
- h) Provide a summary of deleterious consequences.
 - Proposals for new diagnostic categories in Section 3 should comment on the potentially deleterious consequences of their adoption.
- i) Submit the proposal: Attach a full proposal and appendices. Note that only PDF documents can be uploaded

Article IX. Type 7 Proposals: Additions to Other Conditions that May Be a Focus of Clinical Attention

For Type 7 changes involving adding a new condition that may be a focus of clinical attention, you will be asked to provide substantial evidence that the proposed category meets the following requirements:

- (i) The condition or behavior that is the focus of the proposal does not meet the criteria for a mental disorder.
- (ii) Inclusion of the condition would have substantial clinical utility (e.g., it would be useful for management/treatment) or public health utility (e.g., tracking the incidence of the condition would help to develop appropriate public health policies).
- (iii) The occurrence of the condition is not limited to a single diagnostic category or a small number of related categories.
- (iv) The condition can be clearly defined, including behavioral, cognitive, and sociocultural components.
- (v) The prevalence of the condition is frequent enough to warrant being recognized by inclusion.
- a) Provide your identifying information. You will be contacted via the email address you enter if the reviewers require any clarifications or revisions to your proposal
- b) Describe the change you are proposing in a brief paragraph.
- c) Provide a reason for the proposed change.
 - (i) Include a clear summary statement of the rationale for the proposed change, outlining the justification for the change.
 - (ii) Include the historical context for your proposal.
 - (iii) Include a discussion of possible negative consequences of the proposed change and consideration of arguments against the change.
 - (iv) Include a brief section in your proposal outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change.
- d) Specify the magnitude of the proposed change. Addition of a new condition to Other Conditions That May Be A Focus of Clinical Attention is considered a substantial change.
- e) Provide a summary explanation of data on clinical utility:

- (i) Summarize available information about the clinical utility of the proposed condition. If possible, this should be shown in several populations differing by gender, age, ethnicity, etc.
- (ii) Although the types of empirical studies that would be helpful to assess clinical utility are less well established than for validity and reliability, a 2004 paper by First and colleagues (<u>Am J</u> <u>Psychiatry 2004; 161:946–954</u>), developed by an ad hoc subcommittee of the American Psychiatric Association's Committee on Psychiatric Diagnosis and Assessment, provides some guidance.
- (iii) Parameters of clinical utility that could be measured include user acceptability, clinicians' ability to apply the diagnostic criteria accurately, clinicians' adherence to practice guidelines, and ultimately clinical outcomes.
- f) Provide a summary of data on the prevalence of the condition.
 - (i) Information should be summarized in a tabular form.
 - (ii) Include available information about prevalence, demonstrating that the condition is not limited to one or a small number of diagnostic categories and that it appears frequently enough to warrant inclusion.

- g) Provide a summary of data on the reliability with which the condition can be identified, if available.
 - (i) Information should be summarized in a tabular form.
 - (ii) A table with a line for each study that lists the sample size, the reliability (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 is recommended.
 - (iii) If possible, data on reliability should be shown across different populations.
- h) Provide a summary of deleterious consequences.
 - (i) Summarize the available information about the potentially deleterious consequences of the absence of this condition in DSM-5.
 - (ii) Comment on the potentially deleterious consequences of adding this condition to the section on Other Conditions That May Be A Focus of Clinical Attention.
- i) Submit the proposal: Attach the full proposal and appendices. Note that only PDF documents can be uploaded

Article X. Checklist for DSM-5 proposal submission

- a) Please click the submission type(s) for more information:
 - 1. <u>Type 1A</u>: Proposals for changes to an existing diagnostic criteria set that would markedly improve its validity
 - 2. <u>Type 1B</u>: Proposals for changes to an existing diagnostic criteria set that would markedly improve reliability without an undue reduction in validity
 - Type 1C: Proposals for changes to an existing diagnostic criteria set that would markedly improve clinical utility without an undue reduction in validity or reliability
 - 4. <u>Type 1D</u>: Proposals for changes to an existing diagnostic criteria set that would substantially reduce deleterious consequences associated with the criteria set without a reduction in validity
 - 5. <u>Type 2</u>: Proposals for addition of a new diagnostic category or specifier
 - 6. <u>Type 3</u>: Proposals for deletion of an existing diagnostic category or specifier/subtype
 - 7. <u>Type 4</u>: Proposals for corrections and clarifications (including changes to improve the understanding and application of an ambiguous diagnostic criterion, specifier, or text).
 - 8. <u>Type 5</u>: Proposals for changes to the text (not necessitated by changes to diagnostic criteria)
 - 9. <u>Type 6</u>: Proposals for additions to Section 3, Conditions for Further Study
 - 10. <u>Type 7</u>: Proposals for additions to Other Conditions that May Be a Focus of Clinical Attention

Type 1A: Proposals for changes to an existing diagnostic criteria set that would

markedly improve its validity

- a) Submissions of this type must include the items marked by Asterisks
- - (i) \Box Reason for the proposed changes including:
 - 1)
 Clear summary statement of the rationale for the proposed change
 - 2) \Box Historical context for the proposal
 - Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \Box *Validators for the change
 - (iv) 🗌 Reliability
 - (v)

 Clinical utility
 - (vi) 🗌 Deleterious consequences
- c)

 C Prepare tables for:
 - (i)

 Each relevant validator for the change (see categories in the General Guidance). This should be shown in several populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d)
 Upload the complete proposal (in pdf format) at the end that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed change
 - 2) \square *Validators for the change
 - 3) 🗌 Reliability
 - 4) \Box Clinical utility
 - 5)
 Deleterious consequences
 - (iii) \Box Tables for validity and reliability as applicable

- (v)
 Conclusion statement
- (vi) 🗌 Bibliography

TYPE 1B: Proposals for changes to an existing diagnostic criteria set that would

markedly improve reliability without an undue reduction in validity

- a) Submission of this type must include the items marked by Asterisks
- - (i) \Box Reason for the proposed changes including:
 - 1) Clear summary statement of the rationale for the proposed change
 - 2) \Box Historical context for the proposal
 - Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \Box *Validators for the change
 - (iv) 🗆 *Reliability
 - (v)

 Clinical utility
 - (vi) 🗌 Deleterious consequences
- c)

 C Prepare tables for:
 - (i) □ Each relevant validator for the change (see categories in the General Guidance). This should be shown in several populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d)
 Upload the complete proposal (in pdf format) at the end that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed change
 - 2) \square *Validators for the change
 - 3) □ *Reliability
 - 4) \Box Clinical utility
 - 5)
 Deleterious consequences
 - (iii) \Box Tables for validity and reliability as applicable

- (iv) □ Include a brief section outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change
- (v) 🗌 Conclusion statement
- (vi) 🗌 Bibliography

TYPE 1C: Proposals for changes to existing diagnostic criteria set that would markedly improve clinical utility without an undue reduction in validity or reliability

- a) Submission of this type must include the items marked by Asterisks
- - (i) \Box Reason for the proposed changes including:
 - 1) Clear summary statement of the rationale for the proposed change
 - 2) 🗌 Historical context for the proposal
 - 3) Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \square *Validators for the change
 - (iv) 🗌 *Reliability
 - (v) \square *Clinical utility
 - (vi) 🗌 Deleterious consequences
- c) 🗌 Prepare tables for:
 - (i)
 Each relevant validator for the change (see categories in the General Guidance). This should be shown in several different populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d)
 Upload the complete proposal (in pdf format) at the end that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed
 - 2) \Box *Validators for the change
 - 3) 🗌 *Reliability
 - 4) 🗌 *Clinical utility
 - 5)

 Deleterious consequences
- (iii) \Box Tables for validity and reliability as applicable
- (v) 🗌 Conclusion statement
- (vi) 🗌 Bibliography

TYPE 1D: Proposals for changes to existing diagnostic criteria set that would substantially reduce deleterious consequences associated with the criteria set without a reduction in validity

- a) Submission of this type must include the items marked by Asterisks
- - (i) \Box Reason for the proposed changes including:
 - 1) Clear summary statement of the rationale for the proposed change
 - 2) 🗌 Historical context for the proposal
 - 3) Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \Box *Validators for the change
 - (iv) 🗌 Reliability
 - (v)

 Clinical utility
 - (vi) Deleterious consequences
- c)

 C Prepare tables for:
 - (i)

 Each relevant validator for the change (sample in the General Guidance). This should be shown in several different populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d)
 Upload the complete proposal (in pdf format) at the end, that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed change
 - 2) \Box *Validators for the change
 - 3) 🗌 Reliability
 - 4) 🗌 Clinical utility
 - 5) \square *Deleterious consequences

- (iii) \Box Tables for validity and reliability as applicable
- (iv)
 Include a brief section outlining any significant controversies or disagreements among researchers and clinicians in the field concerning the proposed change
- (v) 🗌 Conclusion statement
- (vi) 🗌 Bibliography

TYPE 2: Proposals for addition of a new diagnostic category or specifier

- a) Submission of this type must include the items marked by Asterisks
- - (i) \square *Reason for the proposed changes including:
 - 1)
 Clear summary statement of the rationale for the proposed change
 - 2) \Box Historical context for the proposal
 - 3) Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \square *Validators for the change
 - (iv) 🗌 *Reliability
 - (v) \square *Clinical utility
 - (vi) 🗌 Deleterious consequences
- - (i)
 Each relevant validator for the change (see categories in the General Guidance). This should be shown in several different populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d) \Box Upload the complete proposal (in pdf format) at the end, that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed change
 - 2) \Box *Validators for the change
 - 3) 🗌 *Reliability
 - 4) \square *Clinical utility
 - 5) \Box Deleterious consequences
 - (iii) \Box Tables for validity and reliability as applicable

- (iv)
 Include a brief section outlining any significant
 controversies or disagreements among researchers and
 clinicians in the field concerning the proposed change
- (v) \Box Conclusion statement
- (vi) 🗌 Bibliography

TYPE 3: Proposals for deletion of an existing diagnostic category or

specifier/subtype

- a) Submission of this type must include the items marked by Asterisks
- - (i) \Box Reason for the proposed changes including:
 - 1)
 Clear summary statement of the rationale for the proposed change
 - 2) \Box Historical context for the proposal
 - Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \Box *Validators for the change
 - (iv) \Box Reliability
 - (v) \square *Clinical utility
 - (vi) Deleterious consequences
- c)

 C Prepare tables for:

 - (ii) 🗌 Reliability
- d)
 Upload the complete proposal (in pdf format) at the end that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed change
 - 2) \Box *Validators for the change
 - 3) 🗌 Reliability
 - 4) \Box *Clinical utility
 - 5) \square *Deleterious consequences
 - (iii) \Box Tables for validity and reliability as applicable

- (iv)
 Include a brief section outlining any significant
 controversies or disagreements among researchers and
 clinicians in the field concerning the proposed change
- (v) \Box Conclusion statement
- (vi) 🗌 Bibliography

TYPE 4: Proposals for corrections and clarifications (including changes to improve the understanding and application of an ambiguous diagnostic

criterion, specifier, or text)

Proposals for this type of change do not require the rigorous scientific evidence that must be included in proposals for Type 1,2,3,6, or 7 changes. For proposals for making additions, deletions, or changes to a diagnostic criteria set (including subtypes or specifiers), or if your proposal has the potential to have an impact on caseness, go back to the initial DSM Proposal Submission Portal and choose a Type 1,2,3,6, or 7 change when prompted.

- a) \Box Indicate the type of correction or clarification your proposal addresses:
 - (i) Ambiguity or lack of clarity in the wording of criteria set or text, or
 - (ii) Inconsistencies or contradictions within the text or criteria (for example, the descriptive text conflicts with the criteria for a disorder), or
 - (iii) Errors of omission or inadvertent inclusion (for example, an inadvertent omission of a disorder in the "not better explained by" list as part of the exclusion criteria for a diagnosis)
- b)
 Succinctly describe the correction or clarification that you are proposing, and indicate the relevant DSM-5 page number to which it applies, or if referencing the online version, the category and title under which it appears.

TYPE 5: Proposals for changes to the text (not necessitated by changes to

diagnostic criteria)

- a) \Box Indicate the type of text change your proposal addresses:
 - (i) The current text could result in errors in diagnosis, which would be avoided by the proposed change(s)
 - (ii) The current text could lead to other harms to patients, which would be avoided by the proposed change(s)
 - (iii) The current text reflects a clear and significant error of fact

- (ii) Empirical evidence that such errors occur and, if available, how the proposed change would avoid them.

Type 6: Proposals for additions to Section 3, Conditions for Further Study

- a) Submission of this type must include the items marked by Asterisks
- - (i) \Box Reason for the proposed changes including:
 - 1) Clear summary statement of the rationale for the proposed change
 - 2) \Box Historical context for the proposal
 - 3) Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \Box *Validators for the change
 - (iv) 🗌 Reliability
 - (v) \square *Clinical utility
 - (vi) Deleterious consequences
- - (i)

 Each relevant validator for the change (see categories in the General Guidance). This should be shown in several different populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d) \Box Upload the complete proposal (in pdf format) at the end that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1)
 Magnitude of the proposed change
 - 2) \Box *Validators for the change
 - 3) 🗌 Reliability
 - 4) \square *Clinical utility
 - 5) \square *Deleterious consequences
 - (iii) \Box Tables for validity and reliability as applicable

- (iv)
 Include a brief section outlining any significant
 controversies or disagreements among researchers and
 clinicians in the field concerning the proposed change
- (v) \Box Conclusion statement
- (vi) 🗌 Bibliography

Type 7: Proposals for additions to Other Conditions that May Be a Focus of Clinical Attention

- a) Submission of this type must include the items marked by Asterisks
- - (i) \square *Reason for the proposed changes including:
 - 1) Clear summary statement of the rationale for the proposed change
 - 2) \Box Historical context for the proposal
 - 3) Discussion of possible negative consequences of the proposed change and consideration of arguments against the change
 - (ii) \Box Magnitude of the proposed change
 - (iii) \square *Prevalence of the condition
 - (iv) 🗌 Reliability

 - (vi) 🗌 Deleterious consequences
- c)

 C Prepare tables for:
 - (i)

 Each relevant validator for the change (see categories in the General Guidance). This should be shown in several populations differing by gender, age, ethnicity, etc.
 - (ii) 🗌 Reliability
- d) \Box Upload the complete proposal (in pdf format) at the end, that should include:

 - (ii) □ Subheadings containing complete information included under each section as outlined in the General Guidance for:
 - 1) \Box Magnitude of the proposed change
 - 2) \square *Prevalence of the condition
 - 3) 🗌 Reliability
 - 4) \square *Clinical utility
 - 5)
 Deleterious consequences

- (iv)
 Include a brief section outlining any significant
 controversies or disagreements among researchers and
 clinicians in the field concerning the proposed change
- (v) \Box Conclusion statement
- (vi) 🗌 Bibliography

Article XI. Summary of 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 an 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, 6 and 7 Proposals

All complete, substantive proposals (i.e., Types 1, 2, 3, 5, 6, and 7) 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 a 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, consult with experts in the relevant area if necessary, 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 the 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 Assembly and the Board of Trustees. **To decide to forward a proposal to the Assembly and the Board of Trustees**, **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 Assembly and Board of Trustees: If a proposal is approved by the Assembly and Board of Trustees, the Review Committee that considered the proposal would be asked to develop whatever text changes are needed in the DSM to reflect the approved change in criteria set. The Steering Committee will review and approve those changes prior to forwarding them for inclusion in an updated version of the DSM.