

DSM-5 Field Trials in Academic or Large Clinic Settings

Frequently Asked Questions

1. What is the actual timeline for the DSM-5 Field Trials?

The DSM-5 Field Trials will begin in the summer of 2010 (i.e., June 1, 2010) and continue through to February 28, 2011. This 9-month study period includes:

- 2 months of site preparation activities such as clinician and research coordinator training and submission of IRB application; and
- a 4½-month recruitment period running from August 1, 2010, to December 15, 2010.
- The recruitment period and the period of active data collection will greatly overlap. Given the 1-2 weeks between the time of obtaining written consent and the patient's first study visit, it is anticipated that active data collection will begin around August 15, 2010, and continue until February 28, 2011.

2. Why is a standard protocol being used for the DSM-5 Field Trials across study sites?

A standard protocol is being used to enhance our abilities to compare results across study sites.

3. Can clinicians in non-psychiatry disciplines, such as psychologists, clinical social workers, and nurse practitioners, participate as the study clinicians in the field trials?

Yes, clinicians such as psychologists, masters-level licensed clinical social workers, and licensed nurse practitioners (i.e., a registered nurse who has completed advanced education such as a minimum of a master's degree) are eligible to participate as clinicians in the DSM-5 Field Trials. In states and sites where licensed clinical psychology counselors are trained and allowed to make diagnoses using DSM, they too can participate as clinicians. All participating clinicians must have training and experience in making DSM diagnoses in clinical settings.

4. Can psychiatry residents participate as clinicians in the field trials?

Yes, advanced psychiatry residents (i.e., 3rd and 4th year) are eligible to participate as clinicians in the DSM-5 Field Trials.

5. Can the principal investigator at a selected field trial site, who is obviously aware of the disorders of interest being field tested in the particular site and the treating clinician of many of the patients at the site, fulfill the role of the existing treating clinician for his/her own patient or that of a new clinician for other patients in these field trials?

No, the PI who is aware of the disorders being tested in the participating site cannot be a clinician in the study. This is important for the unbiased estimation of the test-retest reliability of the proposed DSM-5 diagnostic criteria.

6. Does a site really have to meet the “minimum 8 clinicians” criterion indicated in the protocol in order to participate in the field trials? What if a site with fewer than 8 clinicians is able to complete the field trials while maintaining the integrity of the field trials protocol?

In order to complete the test-retest component of the DSM-5 Field Trials, each enrolled patient needs to see 2-3 clinicians throughout the study, with the greatest demand for clinicians being in study visits 1 and 2. The “minimum 8 clinicians” criterion was included to ensure that participating sites would be able to complete the study while adhering to the methodology outlined in our standardized protocol and without overburdening the clinical staff. Clinical sites that strongly believe and can show that they can complete the requirements of the study despite having fewer than 8 clinicians will not be excluded from participating in the DSM-5 Field Trials.

7. How will the participating clinicians and research coordinator at each site be trained? Who will carry-out the DSM-5 Training? What will the training involve? How much time will the training take?

A 2-3 hour DSM-5 Training Seminar specifically geared towards participating clinicians will be conducted at each participating clinical site by members of the DSM-5 Research Group and Task Force. The training seminar will focus on the major changes in DSM-5 including new disorders, new diagnostic criteria, and the use of cross-cutting dimensional and diagnostic-specific severity measures. In addition, participants will be oriented to the electronic data collection system, including diagnostic checklists, which will be used in DSM-5 Field Trials. Each participating clinician at each study site needs to complete the DSM-5 Training Seminar and complete a brief evaluation questionnaire on the training session. Completion and documentation of training (i.e., completion of a brief evaluation questionnaire) **MUST** occur before the clinician is allowed to serve as a study clinician. Once training is completed, clinicians should familiarize themselves with the protocol materials and use these with several non-study patients (with no data submission) prior to recruitment of patients for the field trials. Participating clinicians must also demonstrate completion of Human Subjects in Research training, such as a Web-based training course approved by the National Institutes of Health. A Web cast of the training seminar will also be available for clinicians to view and complete the associated evaluation questionnaire if new clinicians are added to a particular site after the in-person training seminar.

The site research coordinator will also receive training from the APA research statistician/epidemiologist and the DSM-5 Field Trials project manager to ensure that the DSM-5 Field Trial is implemented in accordance with the field trials protocol. This will include a DSM-5 Field Trials in Academic or Large Clinical Settings Procedural Manual, which will provide step by step instructions on how to recruit, enroll, and follow a patient through each study visit throughout the study. The site research coordinator will also receive training on the administration and scoring of all patient-completed measures as well as on the patient and clinician versions of the Discrepancy Interview Protocol. Over the course of the study, in addition to 2 in-person site visits, the DSM-5 Field Trials project manager will also have monthly “GoToMeeting” conferences with the site research coordinators across the various study sites for training updates and to ensure ongoing adherence with the study protocol.

8. Do the control groups, as specified in the protocol for DSM-5 Field Trials in Academic or Large Clinical Settings, have to be samples of healthy, community controls?

No, the control groups should not be healthy community controls. In fact, the control group at each site in this study refers to a group of patients **without** the disorders of interest being tested in that particular site. This group of patients **without** the disorders of interest will serve as a comparison group.

9. Is the study sample limited to only outpatients?

No, the study sample is not limited to only outpatients. However, sites that are proposing to recruit and enroll inpatients must have a system in place to track their patients to ensure completion of the follow-up study visits, preferably offering inpatients follow-up treatment as outpatients at the same site after discharge.

10. The study protocol indicated that each diagnostic group will consist of 50 new and existing patients. Does this mean that a site will have to enroll 50 new and 50 existing patients per diagnostic group?

No. The study protocol actually states that each diagnostic group will consist of 50 new and existing patients **combined**.

11. The DSM-5 Field Trials protocol indicated that patients will be stratified based on their primary DSM-IV Axis I or II disorders assigned by the treating clinician and assessed using the DSM-5 diagnostic criteria with a new clinician conducting the clinical interview. Which DSM-IV diagnostic criteria will be used for the stratification of patients who are being sampled for the testing of a new disorder (e.g., Temper Dysregulation Dysphoria [TDD], pre-school PTSD, Non-Suicidal Self-Injury [NSSI])?

In the case of new disorders, the stratum will be based on DSM-IV diagnostic group(s) with a high probability of getting the new disorder (e.g., for TDD the stratum might consist of individuals with pediatric bipolar, bipolar NOS, ODD, and/or ADHD). However, in such cases it will be helpful to include the other disorders in the stratum as diagnoses of interest. In such cases the sample size of the stratum may need to be increased.

12. If a patient has comorbid mental disorders and more than one of those disorders are being tested at the site, can he/she be stratified into more than one diagnostic group?

No. Such a patient can be stratified to any of the diagnostic group but NOT into more than one. In such instances, the site research coordinator may want to stratify the patient into the diagnostic group that has a lower prevalence in the setting and therefore more difficult to fulfill the required sample size.

13. In the DSM-Field Trials protocol, a 4-12 week study visit is included to assess “sensitivity/responsiveness to change”. For the disorders that can be tested in my site, it is unreasonable to expect a change in diagnosis over such a short period of time. Is this the intent of the 4-12 week study visit?

No, the intent of the 4-12 week study visit that is included in the DSM-5 Field Trials is to assess sensitivity/responsiveness to change of the cross-cutting and diagnostic-specific severity dimensional measures **NOT** the diagnostic criteria.

14. Do the patients who are sampled for the DSM-5 Field Trials have to be restricted to that study or can they come from an ongoing study (i.e., piggy-back onto an ongoing study)?

Patients who are sampled for the DSM-5 Field Trials should ideally be restricted to that study in order to keep the study conditions consistent across the field trial study sites. The study conditions, particularly in terms of sampling, measures given to the patients, and the measures that the clinicians need to complete, must remain constant across the field trial study sites especially for visits 1 and 2. The data from visits 1 and 2 are needed for the assessment of the reliability of the DSM-5 diagnostic criteria and the dimensional measures. However, if a patient needs to be included in any other study, this needs to be done in such a way that it does not affect the clinician's or the patient's ability to fully participate in the DSM-5 protocol.

15. Can clinics/sites add their own measures to the study?

The measures given to patients and those that must be completed by the interview clinicians at study visits 1 and 2 must be consistent across all field trial sites to allow us to compare results across sites. This is important because these two visits will be used to assess the test-retest reliability of the measures and the proposed DSM-5 diagnostic criteria. Gathering of additional information may change the responses to the questions required in the trial. There is more flexibility for additional measures following data collection at visit 3, when all the field trial data have been completed. However, we need to know that you are intending to add such data. Therefore, if study sites would like us to consider the addition of their own measures at visit 3, these measures should be submitted to the APA for review.

16. In addition to the specific childhood disorders that are listed in the document "Disorders for Large Academic Clinic Settings Field Trials" that is posted on the Web site (www.dsm5.org), will other categories of disorders (e.g., major depressive disorder, bipolar disorder) also get tested in children?

The specific childhood disorders listed in this document were the ones identified by the respective DSM-5 Work Groups as disorders in need of testing and as such are considered high priority disorders for this round of field trials. Limited resources affect our ability to field test every single disorder. However, if a site has the capacity to test other disorders in child and adolescent populations, this should be noted in the site's proposal. If financial resources and logistical considerations permit, field trials of these other disorders will be considered after review and decisions have been made with the high priority disorders.

17. Will the assessing clinicians at a particular study site be told which range of disorders to look for in the patients they are evaluating?

No. The aim of the DSM-5 Field Trials is to determine how the proposed diagnostic criteria function in the real world in terms of feasibility, clinical utility, reliability, and where possible, convergent validity. As such, it is important that the assessing clinicians remain blind to the disorders of interest at the particular site. A clinician who is evaluating a patient will have the choice to use whichever diagnostic checklist he/she decides is necessary to complete based on the patient's presenting symptomatology.

18. Do you have an estimate of the amount of time that would be required (face-to-face between the clinician and patient) for each of the three visits?

The face-to-face time between the clinician and patient would be between 60-75 minutes for visits 1 and 2 since these visits will involve reviewing the patient completed measures, completing the indicated clinician-rated dimensional measures, and clinical evaluating and diagnosing (one or more diagnoses) of the patient. Therefore, given that 45-60 minutes is the typical length of time for a thorough psychiatric evaluation, review and completion of the study measures will add an additional 15 minutes to the typical evaluation time. The face-to-face time for visit 3 is less and will range from 15-30 minutes for the clinician to review the results of the patient-rated measures and complete the indicated clinician-rated level 2 cross-cutting and diagnostic-specific severity measures (with each of these measures being relatively brief [i.e., 1-10 questions]).

19. Will the individual sites be responsible for carrying out the statistical analyses indicated in the field trial protocol or will the analyses be carried out by the APA only?

APA will be the data coordinating site for the field trials and initial data analyses for the DSM-5 Field Trials will be conducted centrally by the APA, with input from the field trial sites and DSM-5 Work Groups. However, as indicated in item number 12 above, after data analyses for the principal publications, each site will retain the right to publish subsequent analyses of their own data sets.

20. Can we use the data for our own analyses/publications?

As we indicated in the protocol (i.e., Section 1.7: Dissemination Strategy), after data analyses for the principal publications, each site will retain the right to publish subsequent analyses of their own data sets. A Data Use and Publication Policy will be developed by the APA and participating field trial sites after sites are selected.

21. What do you mean by “research infrastructure” (i.e., how sophisticated does my research infrastructure have to be? Is it necessary that I have had past experience conducting clinical trials?)?

It is preferred but not essential that study sites have past experience conducting clinical trials. Sites with such past experiences will be given priority. However, as long as a site has experience in conducting research studies and can demonstrate their ability to meet DSM-5 Field Trail site requirements, they may be eligible to participate.

22. Is the 10% administrative cost the equivalent to the indirect cost typically provided by NIH/NIMH grants?

The 10% administrative costs for these contracts do refer to institutional overhead costs. As a non-profit grant funding organizations, the APA is not in a financial position to fund indirect costs at levels given with NIH grants.

23. I am in a small group practice that lacks the research infrastructure to participate in the DSM-5 Field Trials in Academic or Large Clinic Settings but would like to participate in the field trials. Is there a way for clinicians like myself who are in small group or solo practices to participate in the DSM-5 Field Trials?

A second field trial for routine clinical practice settings will be conducted separately. This additional field trial will focus on clinical utility, feasibility, and sensitivity to change (of the cross-cutting and diagnosis severity dimensional measures) but without a test-retest or validity component. We are currently recruiting clinicians for this additional field trial. If you are interested in participating in this additional field trial you can go to the www.dsm5.org Web site and click on the “Participate in Field Trials” link or send an email to aparesearch@psych.org to indicate your interest. The protocol for DSM-5 Field Trials in Routine Clinical Care Settings is now available at www.dsm5.org (i.e., go to the **What’s New** section on the right of the screen and click on “**DSM-5 Field Trial Protocol for Routine Clinical Practice Settings**”).

24. I am at a large clinical or academic site that is outside the U.S. and Canada where English is not the primary language, but my site is interested in participating in the DSM-5 Field Trials. Is this possible?

We are currently focusing our field trial efforts on U.S. and Canadian sites. We do, however, recognize the value of experienced institutes in other countries. As such, the possibility of inclusion of international sites will be considered. However, issues related to contractual implications and translation requirements need to be discussed by the DSM-5 Field Trial Team. Therefore, international sites are asked to contact us with a detailed description of their site, the need for and capacity to translate patient and clinician materials, the disorders that can be field tested, and the research infrastructure in place to support the study.