FREQUENTLY ASKED QUESTIONS: DSM-5 FIELD TRIALS

What are the DSM-5 Field Trials and why are they conducted?

Field trials are a way for the DSM-5 Work Groups to test the proposed diagnostic criteria in a real-world clinical setting. The DSM-5 field trials will begin in December 2010 and will continue until the end of August 2011.

For the diagnostic criteria that are being evaluated, the results of the field trials will help answer:

- **Feasibility**: are the proposed criteria easy for clinicians to understand and to use?
- **Clinical Utility**: do the proposed criteria do a good job in describing patients' psychiatric problems and help clinicians make decisions about treatment plans?
- **Reliability**: are the same conclusions reached consistently when the criteria are used by different clinicians with the same patients via observation of the same clinical interview or via independent interviews with a short time delay (i.e., at least 4 hours but no greater than 2 weeks between the different interviews)?
- **Validity**: how accurately do the diagnostic criteria reflect the mental disorders they are designed to describe?

In addition, the field trials will help assess "severity measures" — questionnaires and other tools intended to help clinicians evaluate how severe the symptoms of an individual are on a rating scale, as well as "cross-cutting dimensional measures" — tools for assessing symptoms that occur across a wide range of diagnoses, such as anxiety or sleep problems (for example, an individual with depression may also experience anxiety, or someone with a primary diagnosis of schizophrenia may also experience insomnia). Assessments of cross-cutting dimensions can help clinicians assess a full range of symptoms, even those that may be outside the primary diagnosis. Field trials will help determine whether the proposed severity measures and cross-cutting dimensional measures provide useful information for clinicians and patients, and whether they capture changes in symptom severity over time to help clinicians evaluate progress with treatment.

How can psychiatrists and other mental health clinicians take part in the field trials?

The field trials will take place in both academic and in non-academic clinical practice settings. The field trials in non-academic practice settings will be conducted by two groups of clinicians. The DSM-5 team will work with the APA Practice Research Network (PRN) staff to recruit a random sample of 1,500 psychiatrists (general psychiatrists as well as specialized geriatric, addiction, consultation and liaison, and child psychiatrists) who will be selected from the American Medical Association's Masterfile of Physicians. The DSM-5/PRN team will also recruit another 3,500 volunteer clinicians including 1,000 psychiatrists, 500 psychologists, 500 advanced practice psychiatric nurses, 500 licensed counselors, 500 licensed marriage and family therapists, and 500 licensed clinical social workers. While most of the field trial sites will be in the U.S., the DSM-5 team hopes to collaborate with international sites as well. To

participate, all clinicians must have previous training and experience in making DSM diagnoses in clinical settings.

All DSM-5 field trial participants must complete a training session that includes "Human Subjects in Research" training. The training session will also 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. Participating clinicians who have already completed Human Subjects in Research training and have supporting documentation will not be required to complete the "Human Subjects in Research" component of the DSM-5 field trials training session.

What happens during field trials?

For the field trials in academic settings, different clinicians will evaluate each patient participant at different stages of treatment using the proposed DSM-5 diagnostic criteria and dimensional assessments. The evaluations begin with an initial baseline assessment and are repeated in follow-up visits at least 4 hours and up to2 weeks later (reliability), and finally at 4-12 weeks to test the responsiveness of the severity measures to changes in clinical status (clinical utility). Both patients and clinicians will be asked to assess the "user-friendliness" of relevant components of the DSM-5 criteria and dimensional assessments (feasibility). Some study interviews will be video recorded for review by an expert panel (validity).

For the field trials in non-academic settings, each clinician will evaluate two patients at different stages of treatment using the proposed DSM-5 diagnostic criteria and dimensional assessments. Each patient will be evaluated at two different times: a baseline assessment and a second assessment 4-12 weeks later. Clinicians and patients will be asked to assess the feasibility of the DSM-5 assessments, as is done in the academic settings. The second visit will allow the clinician to document the clinical utility of the follow-up assessments.

The DSM-5 Field Trials team will receive the data and will analyze and disseminate the results in a number of ways. The results will be presented at scientific meetings and shared with professional and consumer groups for their feedback to inform the DSM-5 process. Reports will also be published in peer-reviewed scientific journals and DSM-5 source books. Upon evaluation of the results of the field trials, and in response to feedback received from patients, consumer advocacy groups, and the public, the DSM-5 Work Groups may decide to revise the diagnostic criteria or dimensional measures.

How are patients in the field trials affected by the study?

Both new and existing patients of participating clinicians are eligible to participate in the DSM-5 field trials. All patients in the field trials must give their written informed consent to participate in the field trials. For children, parents or legal guardians must give written consent, and for some older adults, substitute decision makers must provide written consent. There are no certain benefits to patients who

participate in the field trials. Patients participating in the field trials may appreciate the knowledge that they are helping to modify diagnostic assessments for future patients. The new assessments being tested in the field trials also may reveal to the clinician additional helpful information about the patient. The risks of participating in the study are low and will be explained to the patient as part of the consent process. The field trials will involve extra time for patients at their visits. Patients are free to refuse to participate in the field trials, and their refusal will not affect their treatment. Also, participants in the field trials may withdraw their consent to participate at any time without any effects on their current or future treatment.