Summary of Information Needed for Proposals Responding to RFP on

DSM-5 Field Trials – 4/22/10

The following outline summarizes the minimum information needed for review of proposals submitted for DSM-5 field trials. This outline is taken directly from the RFP released earlier. The RFP, Field Trial Protocol, and a Frequently Asked Questions document are available on www.dsm5.org. Applicants should review these documents.

Applicants are encouraged to be succinct in their proposals, but should include any additional information that they feel would be helpful in the evaluation of their proposals, and carefully explain any deviations from the planned study protocol that would be necessary at their sites.

Site Description: The proposal needs to include a description of the site. The site description should include information on the type of site, other site characteristics and the prevalence and types of mental disorders typically seen in the setting.

a) **Type of site:** Please specify the type of site that will be used for the field trial. The DSM-5 Task Force is requesting proposals from academic and large general psychiatric, mental health specialty, and medical specialty settings with dedicated personnel for mental health evaluation and treatment.

b) **Other site characteristics**: The proposal should specify whether the site is an outpatient, inpatient, combined in- and outpatient, or other type of setting. Other special characteristics such as forensic settings, VA sites, etc. should be noted.

c) **Types and distribution of mental disorders:** The proposal should include information on the types and distribution of mental disorders typically seen in the setting.

Timeline: The proposal should confirm that the site is capable of conducting the field trials according to the timeline set forth in the RFP (i.e., a 9 month study period, which includes a 2 month site preparation/pre-data collection period during which time the IRB process will be completed, a 4½ month patient recruitment period, and a data collection period that overlaps with the patient recruitment period).

Disorders to be studied: The target disorders (minimum 2, maximum 5) proposed for the site's field trials should be specified. It would be helpful to note if patients with other disorders of interest are available at your site that could meet criteria for field trial testing.

Patient population: Characteristics of the patient population(s) proposed for trials should be documented, such as age range (child, adolescent, general adult, geriatric, or some combination) and sex distribution. Information on race/ethnic/cultural distribution will be helpful.

Sample size: The site's ability to meet the specified sample sizes for the disorder and control groups during the 4½ month recruitment period should be affirmed. Patient flow/volume statistics at the site will be helpful. If specified sample sizes cannot be met, justification for lower sample size (e.g., very low prevalence of disorder in the general population; rarity of

disorder in treatment settings, etc.) and attainable sample sizes for the disorder(s) studied at the site should be provided

Ability to follow study protocol: The site's ability to conform to the study protocol outlined in the RFP should be affirmed in the proposal. This includes:

- Documentation of the site's research experience and current research infrastructure. This includes the ability to retain Research Coordinator time from existing staff, thereby reducing the need to hire a new untrained Research Coordinator at the site.
- Readiness of site to participate in the June 1 – July 31, 2010 pre-data collection period of this 9 month field trials with staff availability for site preparation and training.
- Feasibility of scheduling the three patient visits according to guidelines in the RFP and study protocol.
- The site's capacity to use a Web-based electronic data collection system, including Wi-Fi capabilities and other internet connectivity, level of familiarity of staff with computers and clinical electronic data systems.

Clinician staffing: The number of clinicians available to participate in the field trials must be specified. A minimum of 8 participating clinicians per site is recommended; fewer clinicians at a site should be justified. Multiple clinicians need to be available in participating sites to: i) enable the reliability component of the study, which requires at least 2 clinicians who have not seen the patient previously (3 clinicians for existing patients); ii) review each patient's self-rated cross-cutting measures (e.g., PROMIS measures); and iii) provide DSM-5 diagnoses using a diagnostic criteria checklist, and associated symptom severity ratings at the baseline and the 1-2 week follow-up visits. The disciplines and levels of training for the participating clinicians should be provided.

IRB approval: Information on the IRB schedule over the next three months and the typical length of time between IRB submissions and approvals at your site should be provided. In particular, details of the site's anticipated IRB process for reviewing the field trials protocol should be provided. Particularly important is the feasibility of acquiring rapid IRB approval. APA will provide assistance to each site that is chosen for the field trials to facilitate IRB approval, including documents on the study protocol, consent forms, and so on that can be modified as needed to fit individual IRB requirements.

Budget: Funding for the field trial sites will be supported through contracts between the sites and the APA. Using guidelines set forth in the RFP, a budget must be submitted for the site.

Contact Information and Proposal Submission: The proposal is due at the APA by the **close of business (5:00 p.m.) on April 30, 2010**. The application must be submitted to both:

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If you have any questions regarding the RFP, please feel free to contact either **Drs. Narrow or Clarke** using the contact information above.