SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **10/31/2012**

Application Number: **1 R01 MH100155-01**

Principal Investigator

GIBBONS, ROBERT D PHD

Applicant Organization: UNIVERSITY OF CHICAGO

Review Group: **CPDD**
Child Psychopathology and Developmental Disabilities Study Section

Meeting Date: **10/18/2012**
Council: **JAN 2013**
Requested Start: **04/01/2013**

RFA/PA: **PA11-260**
PCC: **B4-TBX**

Dual IC(s): **HD**

Project Title: **A New Statistical Paradigm for Measuring Psychopathology Dimensions in Youth**

SRG Action: **Impact Score: 10 Percentile: 3**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Children: **2A-Only Children, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	472,200	718,622
2	497,085	756,494
3	494,844	753,083
4	499,574	760,281
5	498,617	758,825
TOTAL	2,462,320	3,747,305

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R01MH100155-01 Gibbons, Robert

RESUME AND SUMMARY OF DISCUSSION: The proposed research utilizes item response theory and new statistical methodology to create a computerized adaptive test (Y-CAT MH) to measure child and adolescent psychopathology severity. The significance of the new measure lies in its ability to assess symptom severity quickly with fewer questions than traditional instruments as it dynamically selects a small and optimal set of items for each individual. Strengths of the application include the Principal Investigator's expertise in item response theory, the substantial expertise of the research team in both biostatistics and psychopathology, their experience with the development of a similar instrument for adults, and the critical need for such a measure in both research and clinical settings. The use of vertical scaling to address developmental issues and the inclusion of an exploratory aim to investigate rDOC constructs are significant strengths as well. Minor weaknesses focus on questions of the effects of more rapid diagnosis on treatment and improved function, and on insufficient detail regarding analysis of rDOC versus Y-CAT MH categories. During discussion, panel members saw tremendous advantage in a measure that not only was efficient and had enormous clinical utility but could also be used within a research study as a consistent measure of psychopathology across developmental periods. Overall, this is an extremely innovative project from a world-class research team addressing a highly significant need in both clinical and research settings; success would yield a significant shift in psychological assessment methods and have a high impact on the field.

DESCRIPTION (provided by applicant): We propose to develop, test, and apply a new computerized adaptive testing approach to measuring severity of depression, anxiety, mania, disruptive behavior, and attention-deficit/hyperactivity disorders in children and adolescents (9-17 years). This proposal contributes both methodologically and scientifically to research on the assessment of pediatric psychopathology. The proposed work will advance mental health research and improve psychiatric screening and monitoring in primary care. The methodological work proposed in this application is driven by a fundamental scientific challenge that has limited progress in measuring psychopathology in pediatric populations. We need to understand how the measurement of psychopathology in youth changes from childhood through adolescence. Our proposed work includes new statistical methodology for a Computerized Adaptive Test (CAT) based on multidimensional Item Response Theory (IRT) that allows us to tailor the measurement process to each child's developmental level (vertical scaling). The overarching aim of this application is to develop a CAT for children and adolescents that achieves the following goals: Aim 1: Provides dimensional severity scores for depression, mania, anxiety, disruptive behavioral disorders (DBDs), and attention-deficit/hyperactivity disorder (ADHD). Aim 2: Identifies children and adolescents who have symptom severity associated with functional impairment who would potentially benefit from a more extensive diagnostic assessment to evaluate the need for treatment. Aim 3: Uses differential item functioning to identify a set of items that optimally discriminate high and low levels of severity for each of psychopathology dimension equally well for parent and child ratings of that dimension. Aim 4:Accurately predicts DSM categorical diagnoses of major depressive disorder (MDD), ADHD, oppositional defiant disorder (ODD), conduct disorder (CD), anxiety disorders (AD; generalized anxiety disorder, separation anxiety disorder, social phobia, specific phobia), and bipolar disorder (BD). Exploratory Aim: Using the same powerful psychometric strategies, we will take several important steps toward developing and testing of a parallel CAT measure of two of the core biopsychological processes identified in the Research Domain Criteria (RDoC). To achieve these aims, we will develop a bank of approximately 1000 items addressing at different developmental levels symptoms of depression (including a subdomain of suicidality), mania, anxiety, DBDs and ADHD, as well as positive and negative valence RDoC domains. We will then calibrate the item bank using a bifactor IRT model and then develop, test and validate CAT-based administration.

PUBLIC HEALTH RELEVANCE: Computerized adaptive testing (CAT) offers extremely important advantages over traditional measurement techniques in the measurement of youth psychopathology. Traditional psychiatric measurement fixes the number of items and allows measurement precision to

vary from subject to subject. In CAT, the numbers of items and the specific items that are administered are allowed to vary across individuals, but the precision of measurement is fixed. When leveraging a large bank of items, CAT dynamically selects a small and optimal set of items for each individual until a high and predefined level of measurement precision is achieved. This paradigm shift in measurement will impact public health in that it can achieve both substantially increased measurement precision and greatly decreased assessment times, making routine screening and measurement of youth mental health disorders feasible in both mental and physical health settings.

CRITIQUE 1:

Significance: 1
Investigator(s): 1
Innovation: 1
Approach: 1
Environment: 1

Overall Impact: This is an excellent application from a well constructed team of experts in biostatistics and psychopathology who are well positioned to undertake the important work of creating a quick, reliable, and accurate way of diagnosing, establishing impairment, and evaluating treatment response for children and adolescents with mental health concerns. They propose to develop a computerized adaptive testing measure based on item response theory to evaluate the presence/severity of depression, anxiety, disruptive behaviors, and ADHD. They further include the creation of an RDoC CAT measure in the same sample to validate the relationship of the RDoC constructs with the standard psychiatric categories. The need for such a measure(s) is critically important for both research and clinical practice, and the investigators have already demonstrated the utility and applicability of a similar measure developed for adult psychopathologies. How the relationship between the rDoC constructs and the Y-CAT MH categories would be analyzed is not clear, though this is a minor weakness. Given the many strengths of this application, the overall impact of this project is high.

1. Significance:

Strengths

- The application addresses an important need for both research and clinical practice to have a quick, reliable, and accurate way of diagnosing, establishing impairment, and evaluating treatment response in a developmentally appropriate manner for children and adolescents with mental health problems.
- There is likewise a strong need for the development of a common, core set of behavioral constructs that span different stages of development.
- The application also includes as an exploratory aim the development of an rDoC CAT, focusing on positive and negative valence. That these data will be collected in the same sample will allow for the validation of rDoC constructs and their relationship with psychopathological categories.

Weaknesses

- No major weaknesses noted.

2. Investigator(s):

Strengths

- The Principal Investigator, co-investigators, and consultant are all well known within their respective fields, with histories of productive, collaborative, funded work together. Relevant areas of expertise needed to complete the study are represented

Weaknesses

- No major weaknesses noted.

3. Innovation:

Strengths

- Development of a statistical approach to addressing issues of developmental shifts in symptomology while also allowing items to load on more than one primary dimension to accommodate the multidimensional nature of psychopathology
- If successful, would provide advantages over traditional methods of measurement by reducing the number of items needed to be administered to participants/patients while simultaneously maintaining high levels of precision.

Weaknesses

- No major weaknesses noted.

4. Approach:

Strengths

- Construction of a large item back from commonly used and well validated psychiatric scales/interviews
- Consideration and methods of including vertical scaling and a bifactor model

Weaknesses

- How the relationships between rDoC constructs and Y-CAT MH categories will be analyzed is not clear or explicitly stated.

5. Environment:

Strengths

- The research environment and institutional support at all participating sites are excellent and fully capable of supporting the proposed work

Weaknesses

- No major weaknesses noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Protections are adequate

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C2A - Only Children, Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans: Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 2
Environment: 1

Overall Impact: This project uses computerized adaptive testing (CAT) to create a measure of child and adolescent psychopathology (the Y-CAT-MH) that can assess for symptoms and diagnoses with a substantially smaller set of questionnaire items than are present in the standard assessment batteries used today. By streamlining assessment with Item Response Theory techniques and vertical scaling, child and adolescent patients can be readily assessed for mental health problems in standard care medical settings (e.g., physician's offices, ERs). In addition, these techniques can be used to advance research studies of child and adolescent psychopathology and to better link dimensional symptom measures to RDoC constructs of interest. The proposed project will be carried out by leaders in the field of epidemiological research, statistical methods, and child psychopathology. It is supported by a strong network of resources for participant recruitment, data analysis, and dissemination at both the University of Chicago and the University of Pittsburgh. The project builds on similar work that has been recently completed with measures of adult psychopathology, and is well timed with the upcoming release of the DSM-V and the current focus on RDoC measures in developmental psychopathology. If funded, it is likely to have a significant positive impact on the study and treatment of child psychopathology.

1. Significance:

Strengths

- Children in need of mental health services in the US are under-identified and underserved. The development of an assessment tool that can quickly determine diagnoses and need for services across a range of patient care settings can have a very significant impact on child mental health.
- The availability of reliable and valid measures of child psychopathology that can be administered in a short time span would greatly facilitate future research on the etiology and treatment of these conditions.
- The provision of dimensional severity scores is in line with the stated goals of the DSM-V.

- The additional inclusion of RDoC relevant items can help to move the validation of these criteria forward, so that they can better be integrated in future research studies.
- The investigators' previous work with similar measures for adults suggests that dissemination of the Y-CAT-MH is likely to occur very quickly after it is successfully developed, allowing it to have a wide ranging impact on patient care.

Weaknesses

- No major weaknesses noted.

2. Investigator(s):

Strengths

- The Principal Investigator and his collaborators are leaders in the fields of epidemiology and child psychiatry.
- The Principal Investigator is an expert in Item Response Theory techniques, the central component of the proposed study, and similar levels of statistical and methodological expertise are represented across several members of the investigative team
- Several members of the investigative team have collaborated successfully in the past, and in particular the Principal Investigator and Drs. Kupfer and Frank worked successfully to develop the MH-CAT, a computerized adaptive test to assess depressive symptoms, which serves as a model and a springboard for the aims of the proposed study.

Weaknesses

- No major weaknesses noted.

3. Innovation:

Strengths

- This project applies the principles of IRT to the realm of child psychopathology.
- Although it builds upon similar work concerning adult disorders, it adds the technique of vertical scaling to better assess (and account for) the role of developmental changes in the presentation of psychopathology.
- Exploratory analyses introduce the use of RDoC items and allow for their assessment across a large sample of youth, who are also being measured in terms of traditional measures and categories of disorder.

Weaknesses

- The "gold standard" for the measurement of child psychopathology is based on the traditional set of ICD and DSM criteria.

4. Approach:

Strengths

- The study includes two waves of data collection - the first to establish the items and administration details for the Y-CAT-MH, and the second to validate the test.
- Both treatment-referred and community controls will be included, providing a range of symptoms across the samples.

- Similar procedures have been used to examine adult psychopathology (i.e., the bi-factor model of psychopathology), and this project benefits from previous knowledge gained from similar statistical modeling approaches and scale development.

Weaknesses

- Although the sample size is large and the Principal Investigator states it will provide adequate statistical power, insufficient detail is provided concerning power analyses.
- There is insufficient explanation as to how the age groupings for children versus adolescents (9 to 12 versus 13 to 17) were determined. What is the validity of these age groupings in terms of predicting differences in the presentation of psychopathology?

5. Environment:

Strengths

- Facilities and resources at the University of Chicago and the University of Pittsburgh are excellent.
- Adequate access to potential study participants is available through other funded studies (including community controls from a study of children at risk for bipolar disorder), local Pittsburgh clinics that service children with a variety of mental health conditions, and an established network of nurses who recruit research participants from independent pediatric practices in the greater Pittsburgh area.

Weaknesses

- No major weaknesses noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Risks and benefits for those who participate are clearly delineated. There is inclusion of an item to assess suicidal ideation and a follow-up plan for those who endorse this item.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C2A - Only Children, Acceptable

- The study will include 1400 child participants ages 9 to 17, with ethnic/minority representation reflecting the greater Pittsburgh area.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans: Acceptable

- The investigators plan to share the (de-identified) symptom data that they collect so that other researchers can test rDOC models, IRT hypotheses, etc.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Significance: 3
Investigator(s): 1
Innovation: 1
Approach: 1
Environment: 1

Overall Impact: This is an exciting and innovative application from an exceptional team of investigators. If the aims of the study are achieved, a new approach for psychiatric assessment in children and adolescents may be available that substantially reduces patient and provider burden. The application has many strengths. The problem of accurate/reliable psychiatric diagnosis that takes into consideration development is of considerable public health significance. The investigative team is the best that could be assembled to address this problem. The CAT approach is to assessment in this age range is truly innovative and the notion of a paradigm shift is not overstated. The methodological approach is comprehensive and sophisticated and the settings at University of Chicago and Pittsburgh are ideal to conduct the work. There are some noted concerns, however. With respect to significance, it is not clear how rapid and precise assessment can really be translated into better treatment or improvement in function. While this may seem like a no-brainer, what the project will ultimately do is greatly speed up the time that a child/adolescent receives a reliable psychiatric diagnosis. But this is only one step of several that impede optimal treatment for youth with psychiatric disorders. Some attention is given in the Significance to how the CAT approach could be used to monitor and adjust treatment, but this idea is not further developed. Moreover, the next steps for the work seem to be the simple dissemination of the system to anyone who wants it. A more detailed and programmatic plan for how this powerful tool can be further studied and applied would greatly enhance the significance of the project. The project seems heavily dependent on existing DSM-IV diagnostic categories with no attention given to the possibility of changing criteria for DSM-V. Presumably, the CAT approach could be used to map the item banks onto new categories, but some consideration of the adaptability of the outcomes would be useful. As noted, the team is exceptional, and the “Research Design/Timeline” section provides an overview of how the moving parts work together. Still some investigators are listed as Key Personnel (i.e., have biosketches) but do not show up in the budget justification and vice-versa. As such, it is a little difficult to determine who is doing the work and where. In spite of these weaknesses, which are comparatively minor, this is a very strong application.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Acceptable risks and adequate plan for mitigating

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C2A - Only Children, Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommended budget modifications or possible overlap identified:

- Given the scope and complexity of the project, the budget justification alone made it difficult to ascertain different roles and responsibilities of the investigative team and how they all fit together. An overall organizational/management plan would be useful both from the standpoint of understanding the scientific roles of the team members, but also in evaluating the budget more closely.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE
There are no human subject concerns. Risks are acceptable and adequate protections are in place.

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE
Females and males are included in approximately equal numbers.

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE
Minorities are adequately represented in the study design.

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE
Children 9 to 17 years of age are the focus of this research.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

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Biobehavioral and Behavioral Processes Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
CPDD
October 18, 2012 - October 19, 2012

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.