SUMMARY STATEMENT

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(Privileged Communication) ***Release Date:*** **11/04/2015**

Application Number: **1 K01 MH109836-01**

Principal Investigator

CHA, JIOOK PHD

Applicant Organization: NEW YORK STATE PSYCHIATRIC INSTITUTE

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

Meeting Date: **10/15/2015**
Council: **JAN 2016**
Requested Start: **04/01/2016**

RFA/PA: **PA14-044**
PCC: **BK-TK**

Project Title: **Identification of Neural Correlates of Fear Over-Generalization in Pathological Anxiety in Youth**
SRG Action: **Impact Score: 26**
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	171,500	185,220
2	171,500	185,220
3	171,499	185,219
4	171,499	185,219
TOTAL	685,998	740,878

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.

1K01MH109836-01 Cha, Jiook

RESUME AND SUMMARY OF DISCUSSION: The proposed training and research build on the candidate's strong background in neuroimaging and statistical modeling and provide knowledge and skill development in advanced computational neuroimaging methods and phenomenology of anxiety disorders to support a career investigating the neurobiology of affective disorders. This is an excellent candidate with a strong background in neurobiology and cognitive neuroimaging and with an impressive publication record. The proposed training would allow him to shift his research in a developmentally-informed direction and to garner formal training in advanced neuroimaging methods and analyses. The career development plan is well-organized and provides a combination of coursework and hands-on activities clearly aligned with the candidate's goals. The mentor team is headed by the candidate's current advisor but includes additional researchers to offer a broader perspective on the field, and the institutional commitment to this stellar candidate is evident. The research project addresses fear generalization and its neural correlates within a cutting-edge task-based fMRI study that will allow the candidate to test hypotheses of generalization and over-generalization in pediatric anxiety. There are minor concerns with sample size, comorbidity issues, and the wide age range with insufficient attention to developmental rather than just age factors. During discussion, panel members were in agreement with the many strengths of the candidate, mentors, and training/research plans. Overall, this is an outstanding candidate working within a supportive research environment and proposing an ambitious but feasible training plan and an innovative research project; despite minor weaknesses, the proposed training and research are likely to provide an excellent foundation for a successful independent research career.

DESCRIPTION (provided by applicant): Anxiety disorders, as a group, are the most common mental illnesses in the US, affecting about 25% of adolescents and 18% of adults. Symptoms typically begin in childhood or adolescence. A crucial gap in studies of anxiety is the lack of empirical data linking pediatric anxiety to abnormal brain development. This K01 application presents a program for research and training that will support the applicant on a path towards becoming an NIH-funded independent investigator, focused on the application of a fear generalization paradigm and multi- modal MRI to the study of neurobehavioral mechanisms of pediatric anxiety disorders. The activities proposed in this application build on the candidate's previous training and experience and are set in an environment that includes leading clinicians-researchers and affords vast availability of research resources that will foster his development of expertise in (1) the phenomenology of anxiety disorders; (2) patient-oriented, translational and developmental neuroscience to anxiety; (3) advanced computational neuroimaging; and (4) responsible and ethical conduct in scientific research with vulnerable populations. The current research proposal aims to (Aim #1) investigate fear generalization behavior and its relationship with vmPFC (ventromedial prefrontal cortex) function and corticolimbic connectivity in healthy youth, and (Aim #2) to investigate fear over-generalization behavior and its relationship with vmPFC function and corticolimbic connectivity in youth with pathological anxiety. We hypothesize that childhood anxiety involves fear over-generalization and this fear over-generalization involves abnormal function and connectivity of the corticolimbic system. The present study will use a fear generalization fMRI task and multimodal MRI–diffusion and resting-state fMRI–in three groups of youth across the anxiety spectrum–healthy controls, those with subthreshold anxiety, and those with any DSM-5 anxiety disorders. Successful completion of this study will provide cross-sectional evidence of the influence of pediatric anxiety on fear generalization behavior, vmPFC function, and corticolimbic system connectivity. The multiple units of analysis will help elucidate the brain-behavior relationships underlying fear generalization. This demonstration along with the research expertise developed through this K01 award will support an R01, longitudinal study of youth to track developmental trajectories of fear generalization and pathological anxiety. The line of research will promote the development of neuroimaging markers for early detection and novel intervention for pathological anxiety (NIMH Strategic Objectives 2 & 3).

PUBLIC HEALTH RELEVANCE: Pediatric anxiety disorders are serious disorders not only because they are the most common mental illnesses, but also because it involves development of other debilitating diseases in their later lives, such as depression, substance abuse, and ADHD. This proposal will provide first data regarding relationships among fear over- generalization, corticolimbic dysfunction and abnormal connectivity in pathological pediatric anxiety. These outcomes could lead a way to the development of new interventions, preventive strategies, and targets for developing therapeutics.

CRITIQUE 1:

Candidate: 2
Career Development Plan/Career Goals: 1
Research Plan: 2
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1
Environment Commitment to the Candidate: 1

Overall Impact: This K01 application describes a career development and research plan aimed at preparing the candidate to transition to independence as a translational neuroscientist whose research focuses on the biological and cognitive bases of pathological anxiety in children and adolescents. The interesting research project at the focus of the application is designed to examine associations between fear generalization and both vmPFC function/structure and corticolimbic connectivity in adolescents with normative and pathological levels of anxiety. The candidate has a strong training background in neuroscience and biological systems engineering and a solid rate of publication (14 published journal articles, 2 submitted or in review) in highly competitive journals. The thoughtfully-designed project, for which only minor weaknesses are noted, is embedded in a training plan for the candidate that revolves around developing his expertise in the use of multimodal neuroimaging methods and in conducting research in youth samples. The training plan appears carefully thought out and organized - both the mentorship team and the environment are stellar and appear amply suited to enhance the candidate's preparation to embark on an independent research career. In addition, the proposed study has potential to extend the literature on fear generalization and its neural correlates in a developmental direction, which is an important next step, in light of the key role that fear generalization appears to play in the emergence and maintenance of anxiety disorders. Successful completion of the proposed training plan seems likely to launch the candidate toward a fruitful research career.

1. Candidate:

Strengths

- The candidate brings a strong and notably diverse training background to the proposed training. With degrees in both biological systems engineering and neuroscience, he appears to be unusually well positioned to conduct high impact research in his areas of interest.
- Dr. Cha has produced 14 publications to date, 4 of which are first-authored and appear in such outlets as *Journal of Neuroscience* (n=2), *Neuroscience Letters,* and *Neuropsychopharmacology*; two additional manuscripts are submitted or in revision. His work has been recognized with travel and/or career development awards from ADAA and from the Wisconsin Symposium of Emotion, as well as a pilot research grant. He is newly eligible to apply for federal funding because he has applied for permanent U.S. residency.
- Dr. Cha's commitment to a career as an independent investigator appears clear and he has plotted out a methodical path toward carving out his own research questions and obtaining the training and experience to address them.

- Reference letters are uniformly strong indicating that Dr. Cha is an outstanding candidate characterized by independence, maturity, and drive with potential to make significant contributions to the field.
- The candidate's proposed mentors provide glowing letters noting that Dr. Cha is a very promising young scientist.

Weaknesses

- No major weaknesses noted.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- The candidate articulates career objectives that both build clearly on his prior experience in neuroimaging and statistical modeling and shift his work in a developmentally-informed direction relevant to the proposed research. The proposed career development plan appears likely to position him well for subsequent R01 applications and scientific independence.
- The scope and phasing of the career development plan, while ambitious, appear feasible and are supported by a strong training team that clearly articulates specific commitments to training the candidate.
- The candidate has a strong background in multimodal neuroimaging research on fear generalization and anxiety with adults that the training plan will augment with knowledge about anxiety disorders and translational pediatric research, as well as machine learning, Bayesian Hierarchical Modeling, and sophisticated integration of multimodal imaging data. The proposed study appears appropriate for a candidate at his level of research training and experience, particularly given the diverse range of training experiences the candidate has had already.
- The training plan includes regular meetings with mentors and consultants that are focused on evaluating progress and ensuring that the candidate stays on track in generating planned products.
- The mentor clearly outlines a plan for both formal and informal instruction that is consistent with the candidate's timeline and that appears to be comprehensive, but also to leave adequate time for research-focused activities. Relevant coursework is included at each stage of the award period, particularly with regard to developmental psychopathology and child/adolescent development, as well as advanced statistics.

Weaknesses

- No major weaknesses noted.

3. Research Plan:

Strengths

- The proposed research question, which focuses on associations between fear generalization and both vmPFC function/structure and corticolimbic connectivity in adolescents with normative and pathological levels of anxiety, is a salient and novel extension of the adult literature on the neural correlates of fear generalization, to which the candidate has made notable contributions already. The design is cogent and appears largely technically sound; the proposed aims appear feasible to complete during the proposed time period.

- The proposed research plan builds nicely on the candidate's research to date and is consistent with his articulated career objectives, which revolve around building a research program focused on the neural substrates of pediatric anxiety.
- Although the candidate already has notable experience with multimodal imaging data collection and analysis, the proposed research plan would allow him to apply that experience effectively to the study of youths and to extend his knowledge base to encompass relevant, cutting-edge data analytic approaches.

Weaknesses

- At different points in the application, the proposed sample sizes for mild-to-moderate and moderate-to-severe groups vary from 40 to 50, making it difficult to evaluate the budget and project feasibility accurately.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Dr. Posner, the primary mentor, has a strong track record in the field of neuroimaging research on anxiety and related conditions in youths; his well-documented expertise and productivity, reflected in both a notable publication record and a solid funding history, as well as his experience as the associate training director for research in CUMC's Division of Child and Adolescent Psychiatry, should allow him to provide effective mentorship for the candidate in collaboration with Dr. Simpson, who has an impressive history of mentorship and scholarship.
- Dr. Posner describes a plan for working closely with Dr. Cha to achieve clearly articulated benchmarks and to generate specified research products, including both publications and grant proposals. Dr. Simpson similarly provides a detailed plan for mentorship.
- The team of mentors and consultants has a strong history of collaborative work and the candidate appears to have already laid the groundwork for productive working relationships with each member.
- Dr. Pine's lab developed the fear conditioning paradigms planned for use to test core hypotheses - his inclusion as a consultant should enhance both the candidate's training and the study's potential for success.

Weaknesses

- No major weaknesses noted.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Columbia University's psychiatry department and the NYSPI would provide an outstanding environment for the completion of this proposed training and research plan. Resources are ample, access to productive potential collaborators, and the institutions have a superb track record of supporting candidates during the transition to independence.
- The intellectual environment outlined in the training plan encompasses not only CUMC/NYSPI, but also scientifically high-quality institutions that include NIMH and Stony Brook University, and should provide an excellent setting for the candidate's professional and scientific development.
- The institution endorses a commitment to protect 100% of the candidate's time during the award for completion of the application's training and research goals.

- Columbia has articulated that Dr. Cha will be appointed as an Assistant Professor of Psychiatry in the Division of Child and Adolescent Psychiatry in the Department of Psychiatry in March 2016, regardless of whether the current submission is awarded.

Weaknesses

- No major weaknesses noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- The application clearly outlines adequate protections for research participants. Risks appear acceptable; the plan for addressing the minor potential risks identified seems to be sound.

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

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- The proposed plan includes an RCR course at CUMC (1 hr per week) that examines a broad range of ethical and policy issues relevant to the conduct of research. In addition, the applicant plans to complete a seminar in Applied Psychiatric Ethics and to attend the annual Ethics Symposium at NYSPI. Further RCR training will be conducted in the context of individual meetings with the mentors and with Dr. Rynn, one of the consultants on the proposed training plan.

Comments on Subject Matter (Required):

- The proposed RCR training plan appears to encompass a broad range of relevant topics, including conflict of interest, authorship, data management, human subjects, research misconduct, and research ethics.

Comments on Faculty Participation (Required):

- Both the sponsor and co-sponsor, as well as one of the consultants, will meet regularly with the applicant to discuss RCR-related issues.

Comments on Duration (Required):

- The duration of the proposed training will exceed the minimum of 8 hours.

Comments on Frequency (Required):

- The proposed RCR training includes weekly meetings with the sponsor and with the co-sponsor, as well as several more intensive training experiences (workshops, etc.) distributed throughout the training plan.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Candidate: 2
Career Development Plan/Career Goals: 2
Research Plan: 1
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2
Environment Commitment to the Candidate: 1

Overall Impact: This K01 application is from a very talented candidate who proposes to receive training on and examine fear generalization and over-generalization in youth with anxiety conditions. To date, the candidate has a very strong track record and is likely to be successful in years to come. Moreover, the career and research plans appear very strong. Of note, the candidate proposes a very sophisticated model of anxiety and he will test it with highly cutting-edge analytic methods. The mentors and environment are also very strong. This is one of the premier places to conduct psychiatric research. One concern was that the sponsor is the same individual who is serving as the candidate's postdoctoral advisor. Based on this, the candidate may not be exposed to as many different points of view. This concern is mitigated though by the other outstanding mentors who will advise him. As a result, there seems to be ample opportunity for the candidate to learn from different individuals. In summary, because of the training and research that this application will provide, it is expected to have a high impact on the field.

1. Candidate:

Strengths

- Dr. Cha is an outstanding candidate with an impressive publication history. He has approximately 15 publications, which is an impressive number for a postdoctoral fellow.
- The candidate has pursued a very demanding and sophisticated theoretical model of anxiety during his training.
- His background training is very consistent with what he proposes for his current project.

Weaknesses

- No major weaknesses noted.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- Along with a sophisticated and mechanistic model, the candidate has set out to master a set of very exciting analytic skills.
- He has also assembled a strong team of mentors to help make sure that he will learn the procedures.
- The letters of support are uniformly enthusiastic and it is highly likely that the candidate will receive the stipulated training. If successful, the training will help propel the candidate to the next professional level.

Weaknesses

- No major weaknesses noted.

3. Research Plan:

Strengths

- The candidate has set out to collect data on a very cutting-edge and interesting task-based fMRI study that will allow him to test his hypothesis of generalization and over-generalization in pediatric anxiety.
- Data from the resting state functional connectivity and diffusion MRI will also provide very useful information about the neural circuit of interest.
- The N is modest, which is necessary for a K award, but it will provide very useful and publishable data that will serve as the basis for an R01.

Weaknesses

- No major weaknesses noted.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- The mentors are all very strong.
- The mentors each have a very specific role to play in the candidate’s training.

Weaknesses

- Ideally, the K award sponsor would be someone different than the postdoctoral advisor. In this application, the sponsor and advisor is the same person. This limits the candidate’s exposure to different points of view during training. Nevertheless, the mentoring team is broad and so the candidate will certainly receive other perspectives.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- The institution is outstanding and the research is likely to be accomplished there.
- The institution expects to promote the candidate to assistant professor in the spring of 2016.

Weaknesses

- No major weaknesses noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- The risks are acceptable and the protections are adequate.

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

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically.
- The protocol will include an equal number of males and females as well as a diverse group of subjects.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- The candidate detailed extensive lectures and discussion that will fulfill the requirements.

Comments on Subject Matter (Required):

- The candidate described the subject matter, which will fulfill the requirement.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Faculty, including the mentor, will participate.

Comments on Duration (Required):

- Duration appears to exceed the requirement.

Comments on Frequency (Required):

- Frequency ranges between once per week and once per year depending on the format. This rate is higher than what is mandated.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Candidate: 2

Career Development Plan/Career Goals: 3
Research Plan: 3
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2
Environment Commitment to the Candidate: 1

Overall Impact: The current application proposes to train a recent PhD, Dr. Cha, in the methods and measures of pediatric neuroimaging with a focus on the neural mechanisms associated with fear over-generalization and anxiety in children. Dr. Cha has a promising track record and has had prior success in translating his training into publications. He has garnered the support of a number of well-established researchers, which should increase the odds of success for his training and research plan. His team of mentors is well versed in the core issues at hand and balances relatively new mentors with individuals with long experience mentoring K-level researchers. The training plan is feasible and covers many important components of the study. In the plan, some considerations are not addressed as thoroughly as needed. The recruitment range is quite wide (8 to 17) and developmental considerations are simply equated with age. However, this does not address the specific mechanisms that may be at play with both the early emergence of anxiety and the interplay with neural circuitry and fear learning. There are normative changes in fear processing in this window and it is not clear that the candidate is in a position to incorporate this into the conceptualization of the data. The publication plan (including targeted outlets) assumes data will be quite straightforward and impervious to these issues. There are also some missing details. For example, it is not clear if the samples are yoked in any way with respect to age, gender, etc. Again, this might confound some analyses.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- However, the section is primarily focused on MRI-related concerns. Little to no mention is made of procedures in place to deal with issues of concern that may arise with a developmental sample, particularly if elevated in anxiety.

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

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically.
- The sample will be children ages 8 to 17.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- Formal courses are supplemented with meetings with mentors.

Comments on Subject Matter (Required):

- Misconduct, research participant protection, data sharing, clinic-related issues of concern.

Comments on Faculty Participation (Required):

- The faculty will be involved in didactics supplemented with formal meetings.

Comments on Duration (Required):

- Acceptable amount carried through the duration of the grant.

Comments on Frequency (Required):

- Intervals are acceptable.

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, 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 are adequately represented.

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

Minorities are adequately represented.

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

Adolescents, 8 to 17 years of age, are the focus of this research.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested

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NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the 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. Some applications also receive a percentile

ranking. For details on the review process, see
http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Child Psychopathology and Developmental Disabilities Study Section
Biobehavioral and Behavioral Processes Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
CPDD
October 15, 2015 - October 16, 2015

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