SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **06/24/2016**
Revised Date:

Application Number: **1 K01 MH109836-01A1**

Principal Investigator

CHA, JIOOK

Applicant Organization: NEW YORK STATE PSYCHIATRIC INSTITUTE

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

Meeting Date: **06/13/2016**
Council: **OCT 2016**
Requested Start: **09/01/2016**

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

Project Title: **Neural Correlates of Fear Over-Generalization in Youth with Pathological Anxiety**

SRG Action: **Impact Score:15**
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	171,499	185,219
2	171,499	185,219
3	171,499	185,219
4	171,499	185,219
TOTAL	685,996	740,876

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.

1K01MH109836-01A1 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. Since the first submission, the candidate has published 5 more papers, including 2 as first author, and has received a NARSAD award. 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. In response to review, the minor concerns with sample size, comorbidity issues, the wide age range, and insufficient attention to developmental factors have clearly been addressed. The age range has been narrowed, the sample sizes increased, Tanner staging added, and exclusion criteria now rule out major comorbidities. 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; 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 four--year K01application presents a program for research and training that will support the applicant on a path towards becoming an NIH--funded independent investigator, focused on studying the neural correlates of fear generalization in youth with pathological anxiety using interdisciplinary approaches (affective neuroscience, multimodal neuroimaging, and computational methods). The training plan builds on the candidate's previous training and experience, and capitalizes on a mentorship team and a research environment to foster development of the candidate's expertise in (1) the phenomenology of anxiety disorders;; (2) patient--oriented, translational and developmental neuroscience of anxiety; ; (3) Advanced computational neuroimaging; ; And (4) responsible and ethical conduct in scientific research in vulnerable individuals. The research project will investigate fear generalization behavior and its relationship with vmPFC (ventromedial prefrontal cortex) function and corticolimbic connectivity in healthy youth (Aim #1), and investigate fear over--generalization behavior and its relationship with vmPFC function and corticolimbic connectivity in youth with pathological anxiety (Aim #2). We hypothesize that childhood anxiety involves fear over--generalization and that fear over--generalization involves abnormal function and connectivity of the corticolimbic system. To test these hypotheses, we will use a fear generalization fMRI task and multimodal MRI (structural, diffusion, and functional MRI) in healthy youth without anxiety (n= 25) as well as in youth with pathological anxiety across a spectrum of severity (i.e., those with subthreshold
anxiety [n=25] and those with any DSM--5 anxiety disorder [n=25]). Successful completion of this study will provide cross--sectional evidence of the association of pediatric anxiety with fear generalization behavior, vmPFC function, and corticolimbic system connectivity. The multiple units of analysis will help elucidate brain behavior relationships underlying fear generalization. These data along with the research expertise developed through this K01 award will support a future R01 application to track over time the developmental trajectories of fear generalization and pathological anxiety in youth. The ultimate goal of this line of research is to develop neurobehavioral markers to determine when and where to intervene in anxiety disorders (*NIMH Strategic*

Objective 2) and to promote preventive therapeutic interventions to youth with pathological anxiety (*NIMH Strategic Objective 3*).

PUBLIC HEALTH RELEVANCE Anxiety disorders in youth are very common and presage the development of other debilitating diseases, such as depression and substance abuse. In this proposal, we will test whether anxious youth show over generalization to stimuli conditioned to fear, and to examine the related neural circuitry. Results from this study could lead to the development of new targets for treatment development as well as strategies to prevent the onset of anxiety disorders.

CRITIQUE 1:

Candidate: 1
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 4-year K01 application is from a very talented candidate who proposes to receive training on, and examine the brain bases of, anxiety in 13- to 17-year-old teens. Dr. Cha will use a fear acquisition and extinction paradigm with fMRI to study fear generalization and over-generalization in 3 groups of teens – 25 with low anxiety, 25 with moderate anxiety and 25 with high anxiety. Also, he will use diffusion MRI and resting state-fMRI and skin conductance. The candidate will receive training in phenomenology of anxiety disorders, translational developmental neuroscience of anxiety disorders, and advanced computational neuroimaging, including machine learning. This is a resubmission and the candidate was very responsive to the prior critiques. Dr. Cha received his undergraduate degree in environmental engineering and a master's degree in neurobiology, both in Korea. He then came to the United States and received a PhD in Cognitive Neuroscience from Stony Brook University in 2013 and he then became a fellow at Columbia University working with Dr. Jonathan Posner. The candidate has 17 publications in well-regarded journals, including 3 first author publications in the *Journal of Neuroscience* and a first author publication in *Neuropsychopharmacology*. Also, he recently received a NARSAD Young Investigator's Award. The institution intends to promote the candidate to assistant professor in July of 2016. This is one of the premier places to conduct psychiatric research. The mentors are also very strong. Mild concerns include the following items. The sample size is not ideal. However, the limited budget of the award will not allow for a large sample. This will provide excellent preliminary data for a larger grant. Also, it is unclear how many prior trainees the primary sponsor has mentored. However, with the extensive mentoring experience of the other mentors, this is not a major concern. Because the plans will provide excellent training and data for this very promising candidate, this application 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 17 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 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.
- 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 sample size 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 application.

Weaknesses

- No 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

- It is unclear how much experience the sponsor has had with mentoring.

5. Environment and Institutional Commitment to the Candidate:

Strengths

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

Weaknesses

- No 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
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Including ages < 18; 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)

Resubmission:

- The candidate was very responsive to the comments from the first submission.

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.

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

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

Overall Impact: This is a revision of a K01, from a candidate (Jiook Cha) trained in cognitive neuroscience who wishes to become an independent investigator studying the impact of anxiety on developmental trajectories of fear generalization and their underlying neural systems, in pediatric populations, using functional MRI (fMRI). Dr. Cha is affiliated with Columbia University and the New York State Psychiatric Institute. The candidate has extensive first author publications, excellent mentors and advisors, in addition to a well-designed training program and research project. Prior review was concerned that his primary mentor (Jonathan Posner at Columbia) was also his postdoctoral advisor, this has been addressed by adding an additional mentor (Blair Simpson at Columbia). In addition, concerns were expressed with the research project: the sample size, comorbidity issues, and that the age range was too broad, with attention being paid more to age than developmental stage. All of these issues have been addressed in this resubmission.

1. Candidate:

Strengths

- The candidate has a Ph.D. in cognitive neuroscience, and is currently a fellow in pediatric neuroimaging at Columbia University.
- The candidate has five first author publications, and has co-authored many, in high impact journals (*J of Neuroscience, Neuropsychopharmacology* etc.).
- He had received a Travel and Career Development Leadership Award from the Anxiety and Depression Association of America (ADAA), and a travel award to the Wisconsin Symposium on Emotion.
- He is the recent recipient of a NARSAD Young Investigator Award, and a Research Exchange Fellowship between Columbia University and the University of Glasgow.
- Uniformly strong references letters, mentor support letters, and advisor letters.

Weaknesses

- None noted.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- The candidate wishes to (1) learn the phenomenology of anxiety disorders, (2) acquire expertise in transdiagnostic neuroimaging experimentation in youth with anxiety disorders, and (3) learn up-to-date imaging data analysis technologies.

- His mentor team of Drs. Posner and Simpson is well suited to providing expertise in transdiagnostic neuroimaging experimentation and learn the phenomenology of anxiety disorders, respectively.
- He includes 5 advisors: 2 to advise further on the phenomenology of anxiety disorders; and 3 to advise on up-to-date imaging data analysis technologies.
- Course work and hands-on practicum related to anxiety disorders and pediatric psychopathology. A collaboration with advisor Dr. Stephan in Switzerland (facilitated by NARSAD award) to learn advanced computational methods.
- Attend ADAA and Society for Biological Psychiatry (SOBP) Meeting
- Sufficient time is allowed to reach these training goals and meet with mentors/advisors.
- Courses in responsible conduct of research have been done, and more are included.

Weaknesses

- None noted.

3. Research Plan:

Strengths

- Investigating the significant questions of whether, or not, fear generalization occurs in youth, and what neural systems are involved? And does fear over-generalization occur in youth with pathological anxiety, and if so, what neural abnormalities are involved? The candidate will then have data to submit an R01 to look at longitudinal trajectories.
- Preliminary imaging data in adults, pilot data of fear generalization task in adolescents.
- Age range 13 – 17, participants will be matched on Tanner stage. Girls imaged during early follicular phase. All imaged in the early evening: feasible and helps with potential diurnal variation in hormones.
- Including transdiagnostic anxiety disorders, consistent with RDoC, and specific aims to be addressed. Excluding other psychiatric diagnoses that may differentially impact the circuits of interest.
- Multiple recruitment sources and plans.

Weaknesses

- None noted.

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

Strengths

- Dr. Posner is well suited to mentor Dr. Cha; he is an expert in developmental neuroimaging.
- Dr. Simpson is an expert in anxiety disorders, and is the recent recipient of a K24.
- Dr. Rynn (internal advisor) is an expert in the phenomenology, treatment, and characterization of pediatric anxiety disorders.
- Dr. Pine, Chief of the Section of Development and Affective Neuroscience at NIMH, is a leading expert in applying affective neuroscience, psychophysiological and neuroimaging experimentation to studies of pediatric anxiety.
- Dr. Bowman (internal advisor) is an expert in advanced statistical modeling of neuroimaging.

- Dr. Stephan, Director of the Translational Neuromodeling Unit at ETH Zurich, is an expert in Bayesian modeling in neurobiology.
- Dr. Yoo (Brookhaven National Laboratory) is an expert in “big data” science.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Columbia University and the New York State Psychiatric Institute are excellent sites, suited to doing this research.
- Institutional support letter is strong: while currently a postdoctoral fellow, Dr. Cha will be promoted to a faculty position (Assistant Professor) effective July 2016, independent of this award.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

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
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Including ages < 18; 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):

- There will be formal coursework, university seminars, and one-on-one meetings

Comments on Subject Matter (Required):

- Ethical and policy issues of research; psychiatric ethics

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

- Mentors will engage in training; in addition faculty will lead formal courses

Comments on Duration (Required):

- It appears that it will span the length of the K award.

Comments on Frequency (Required):

- Meetings with mentors will be weekly. Seminars will occurs annually and across semesters.

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

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

Overall Impact: The revised K01 submission is from a highly promising candidate focused on the translational and developmental neuroscience of anxiety in youth. In the specific study, Dr. Cha will focus on fear generalization and over generalization in healthy and anxious adolescents. The candidate has a strong history of publications and has created an effective mentoring team that should continue this trajectory. There are adequate meetings spanning from quarterly, monthly, and weekly, depending on the level of mentorship. This is a strong environment, with needed resources, as evidenced by the preliminary data. There is a clearly described rationale for the design, which may bode well for the transition to an eventual R01. The conceptualization of 'development', here in the form of puberty is not clear in the design of the study. That is, adding a measure of puberty is no more developmental than noting age of participants. Developmental consideration comes in the use of the data to examine mechanistic processes. Indeed, given the age range, it is unlikely that much will come of the puberty measures.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Adequate safeguards are in place.

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
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable

- Inclusion/Exclusion of Children under 18: Including ages < 18; justified scientifically
- Focus is on early anxiety-related mechanisms.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

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

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested

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Footnotes for 1 K01 MH109836-01A1; PI Name: Cha, Jiook

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
06/13/2016 - 06/14/2016

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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.