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SUMMARY STATEMENT
(Privileged Communication)

Release Date: 04/02/2011

Application Number: 1 F31 AA020132-01A1

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Review Group: AA-4
Neuroscience Review Subcommittee

Meeting Date: 03/08/2011
Council: MAY 2011
Requested Start:

PCC: AN J

Project Title: Now versus Later decision Making: Effects of frontal development and alcohol use

Requested: 3 years

Sponsor: Boettiger, Charlotte A
Department: Psychology
Organization: UNIVERSITY OF NORTH CAROLINA CHAPEL HILL
City, State: CHAPEL HILL NORTH CAROLINA

SRG Action: Impact/Priority Score: 20
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: 1A-Both Children and Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

1F31AA020132-01A1 Smith, Christopher

RESUME AND SUMMARY OF DISCUSSION: This application for a National Research Service Award Predoctoral Fellowship requests 36 months of support under the mentorship of Dr. Charlotte Boettiger. The applicant seeks training in functional magnetic resonance imaging (fMRI) acquisition with a focus on impulsivity. The research plan will compare frontostriatal activation to “now relative to later” decision making in non- or light drinking adolescents versus adults, and will determine whether impulsive decision-making in heavy drinking adults is linked to activation in these frontal regions. The applicant was highly responsive to previous critiques by adding Dr. Crews as a mentor, focusing the imaging training to fMRI, and clarifying some methodological details. As a result, the revised application is substantially improved. Overall, there was strong enthusiasm for this excellent application.

DESCRIPTION (provided by applicant): Individuals are at greatest risk for developing an alcohol use disorder (AUD) during late adolescence (Kandel and Logan, 1984; Brown et al., 2008), possibly due to the relative impulsiveness of late adolescents/young adults. Kandel and Logan (1984) have suggested that the decline in heavy alcohol use that typically occurs in the mid-twenties may reflect a maturational or developmental process, as the development of frontal structures implicated in self-regulation and impulse control is complete in humans around the early- to-mid twenties (Giedd, 2004; Hooper et al., 2004; Rubia et al., 2006; Eshel et al., 2007). Although there is general acceptance of the idea that frontal circuits are still maturing in late adolescents no work to date has specifically investigated changes in the function of frontal circuits engaged during Now versus Later decision making, a quantifiable measure of impulsiveness. The proposed studies will compare late adolescents (ages 18-23) and adults (ages 25-40) using functional MRI approaches to identify differences in the brain areas engaged during Now versus Later decision-making. In addition, we will determine whether heavy alcohol use is associated with abnormalities in normally observed age-related differences in these neural circuits. Our central hypothesis is that immaturity in frontal circuits and relatively increased signaling in striato-limbic structures promote impulsive decision making in late adolescents. We will test our central hypothesis via the following Specific Aims: 1) Identify functional differences in frontostriatal circuits associated with Now/Later decision making in late adolescents versus adults. 2) Determine whether the impulsive decision-making observed in heavy drinking adults is associated with signs of functional immaturity in frontal circuits. To achieve the goals of this research plan, a previously validated delay-discounting task (Mitchell et al., 2005; Boettiger et al., 2007) will be used to measure Now/Later decision making behavior in late adolescents and adults in the context of functional MRI. We will seek to determine whether age-dependent differences in the function of brain structures of interest correlate with age-dependent differences in decision-making. These studies will be conducted in both moderate and heavy drinking populations to determine how alcohol use impacts age-related changes in brain structures engaged in Now/Later decision making. This research stands to significantly improve our understanding of the neural underpinnings of changes in decision-making from late adolescence to adulthood, which may bear on why late adolescents are at an increased risk for developing alcohol use disorders. Greater knowledge of the mechanisms underlying risk for developing alcohol use disorders may allow for the development of better treatments or interventions.

PUBLIC HEALTH RELEVANCE: This research project seeks to understand the neurobiological bases for the decline in the tendency to choose smaller, sooner rewards ("Now") over larger, later rewards ("Later") from late adolescence to early adulthood, a tendency that also characterizes individuals with alcohol use disorders. Studying developmental changes in the function of frontal structures that regulate Now/Later decision-making may provide insight into why late adolescents are at increased risk for developing alcohol use disorders, which may in turn aid in the development of new prevention and treatment approaches for this vulnerable age group.

CRITIQUE 1:

Fellowship Applicant: 2

Sponsors, Collaborators, and Consultants: 1

Research Training Plan: 3
Training Potential: 3
Institutional Environment & Commitment to Training: 2

Overall Impact/Merit

This 3-year revised F31 application proposes functional magnetic resonance imaging (fMRI) acquisition with a focus on now versus later decision making. Aim 1 compares 20 18-23 year-olds to 20 25-40 year-olds (all moderate to non-drinkers) in Later relative to Now activation. Aim 2 compares heavy versus light/moderate drinking adults (ages 25-40) on the same task. The proposed work has public health relevance as it may provide information on when in early adulthood a shift in present-focused versus future-focused decision-making occurs, and the degree to which frontal maturation can explain this. The applicant was highly responsive to the initial round of reviews, and this revised F31 3-year application is substantially improved as a result. Importantly, he has added a senior co-sponsor, trimmed the focus to fMRI (removing DTI and structural MRI training and related research hypotheses), and added coursework to the training plan. Other clarifications and rationales were succinctly provided in response to each reviewer comment. The applicant does cite papers in preparation, but does not have yet a peer-reviewed publication.

1. Fellowship Applicant

Strengths

- The applicant is Mr. Christopher Smith, a 3rd year graduate student in psychology (emphasis in neurobiology) at the University of North Carolina at Chapel Hill, in the lab of Dr. Charlotte Boettiger.
- Reference letters are provided by Drs. Judith Grisel, Clyde Hodge, Linda Dykstra, Gabriel Dichter, and Donita Robinson, which describe him as an “outstanding student” “bright” and “genuinely driven”. His application was supported enthusiastically.
- His prior training was in cell and molecular biology and mouse models of depression and anxiety. He now expresses a strong interest in alcohol research and human decision-making.

Weaknesses

- His biosketch still shows 5 posters, but no publications. His application describes that he has papers in preparation. He started graduate school in 2008, so this is not particularly unusual.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The Sponsor is Dr. Charlotte Boettiger, Assistant Professor at UNC-Chapel Hill in the Bowles Center for Alcohol Studies, and an expert in fMRI studies of delayed discounting, impulsivity, and decision-making with applications to addiction. She leads several pilot projects, and is PI on a junior faculty development award on Neuropharmacology of Immediate Reward Bias. While Dr. Boettiger is a relatively new faculty person, she mentors two postdoctoral fellows.
- The Sponsor’s letter details a comprehensive training plan that will provide the applicant with tools for conducting fMRI studies, as well as for presenting results, ethical conduct of research, mentoring undergraduates, and exposure to clinical features of alcohol use disorders.
- Dr. Boettiger is the Sponsor and primary mentor, Dr. Crews will be a Co-Sponsor, and other individuals in his graduate training program at the Bowles Center will be involved in his training (including Drs. Dykstra, Garbutt, Lin, Belger, Carelli, and Zhu) to ensure training in imaging, AUD, statistics, and data presentation.

Weaknesses

- None noted in this revised application.

3. Research Training Plan:

Strengths

- The aims have clear hypotheses, use a well-characterized task developed by the Sponsor, and appear adequately powered.
- Aim 1 is to compare frontostriatal activation to now relative to later decision making in older adolescents versus adults. Aim 2 will determine whether impulsivity decision-making in heavy drinking adults is linked to activation in these frontal regions. Hypotheses are specific to justifiable brain regions.
- The focus on fMRI, and omission of diffusion and structural acquisitions, has provided a more focused application with a more appropriate level of detail for the fMRI acquisition and analysis.

Weaknesses

- It is not clear why coronal acquisitions of the EPI data are used; Figure 2 indicates that the acquisition does not provide whole-brain coverage, leaving off the posterior occipital area. It seems that a fewer number of axial or sagittal slices might provide whole brain coverage.
- It would be nice to see a even more refined neuroanatomic specificity in the hypothesis testing section, but the contrasts and general regions (OFC, PFC) are specified.

4. Training Potential:

Strengths

- The applicant has excellent letters of support.
- Potential is excellent for training in fMRI and neural basis of decision-making and future orientation in the lab of Dr. Boettiger.
- Potential is also very good for the applicant to receive exposure to assessment of alcohol use and related constructs and to understanding the neural features linked to addiction through involvement in the Bowles Center for Alcohol Studies.
- Applicant proposes to take a short course or workshop on neuroimaging techniques, a graduate level biostatistics course, a course on functional anatomy of the human brain, and possibly a course on neuropharmacology of alcohol and substance abuse with Dr. Leslie Morrow.

Weaknesses

- None noted in this revised application.

5. Institutional Environment & Commitment to Training:

Strengths

- The imaging facilities are excellent, and it appears that the applicant will have access to the one of the two research-dedicated scanners (Allegra and/or Trio; one scanner for each experiment).
- The Bowles Center for Alcohol Studies is an outstanding resource for a trainee aspiring to a career in alcohol research.

Weaknesses

- None noted in this revised application.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Appropriate safety precautions are taken for MRI, and verbal consent will be obtained before screening interviews are conducted.

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

C1A - Children and Adults, Acceptable

- Efforts will be taken to ensure that 50% of participants are female, and that the ethnic composition is representative of the Chapel Hill area.

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 applicant has completed a core course on research ethics, and has additional specialty courses planned or underway. Also did CITI online course on research ethics and HIPAA.

Comments on Subject Matter (Required):

- Covered authorship, proper use of animals and humans in research projects, the importance of the institutional review board, and scientific honesty. Taking Graduate School course at UNC (Grad 721) that focuses on concepts, rules, and issues that are central to research ethics

Comments on Faculty Participation (Required):

- Seminars and continuing education through the Curriculum in Neurobiology and Bowles Center for Alcohol Studies, which the sponsor attends.

Comments on Duration (Required):

- not specified

Comments on Frequency (Required):

- not specified

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Fellowship Applicant: 2
Sponsors, Collaborators, and Consultants: 2
Research Training Plan: 2
Training Potential: 1
Institutional Environment & Commitment to Training: 1

Overall Impact/Merit

This revised application was very responsive to the previous review critiques. It addresses a significant public health question by examining differences between older adolescent and adult drinkers in behavioral and brain response in an impulsive decision making task, and whether adult heavy drinkers respond in way that suggests delayed development or 'functional immaturity' of these brain circuits that promote impulsive decisions. The applicant's letters of reference were strong, he has a strong training background, and his career goals are well aligned with the goal of the F31 mechanism. The primary mentor, although somewhat early in her career, has mentoring experience commensurate with her stage, and the ideal scientific skill set to provide the training the applicant desires in neuroimaging and the delay discounting task. The addition of Dr. Crews as a co-sponsor was a reasonable way for the applicant to capitalize on Dr. Boettiger's expertise within the context of a well-established and supportive co-sponsor who insures scientific integration with broad resources of the Bowles Center. Formal training in human brain development was bolstered in this revision. The scope of the research aims was narrowed, resulting in a more focused and feasible research training plan. There was a high level of enthusiasm for this revised application.

1. Fellowship Applicant

Strengths

- The applicant received an undergraduate degree with honors in 2008 in Neuroscience from Furman University, where he gained experience in alcohol research with transgenic mice. The applicant's undergraduate training provides a strong behavioral neuroscience background in alcohol research using animal models which is useful for his transition to human neuroscience research in the alcohol field.
- Referee letters from the applicant's current and undergraduate research mentors highlight his dedication and aptitude for an independent research career. He was described as having strong critical thinking and communication skills and a commitment to a research career in an academic environment. He was described as an outstanding student, self-starter, tenacious.

Weaknesses

- No published journal articles as yet, but this is not a major concern in light of his transition from animal to human neurobiology in June 2009. Since that time, the applicant has four published abstracts, two as first author, and manuscripts in preparation.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The primary sponsor is well suited to provide training in the delay discounting task and the functional neuroimaging (fMRI) that are the foci of the revised application.
- Fulton Crews was added as a co-sponsor. Dr. Crews is a member of the applicant's dissertation committee and Director of the Bowls Center for Alcohol Studies. Drs. Crews and Boettiger have a history of collaborative publication and mentoring, so this was viewed as strengthening both the research and training plan.

Weaknesses

- The primary sponsor's R01 is pending; however she has start-up and other funding to support the proposed neuroimaging.

3. Research Training Plan:

Strengths

- Detailed and appropriate training plan. Coursework at Duke University was added to augment training in developmental cognitive neuroscience and brain anatomy, as well as seminar/course offerings at University of North Carolina.
- The scope of the research was reduced to increase feasibility and depth of training in fMRI. The Specific Aims of the research plan were streamlined to 1) identifying differences in late adolescents (18-23 yr) and adults (25-40 yr) in orbitofrontal cortex and striato-limbic response during now versus later decisions in a delay discounting task and 2) to determine whether heavy drinking adults show functional immaturity in the frontal brain region, similar to the younger age group.
- Preliminary behavioral data in the task showed that there was a decrease in delay discounting at age 24, leading to better differentiation of age group definitions compared to the original application.
- Sponsor affirmed sufficient support for fMRI through her institutional startup funds and K01 mechanism.

Weaknesses

- The revised aims would only appear to work if both young adult and adult samples recruited for Aim 1 have an AUDIT score of < 6, although this inclusion criterion was not indicated in the design. This is in view of the fact that Aim 2 involves recruiting 20 additional adults with AUDIT scores GE 6 for comparison. Given that both drinking and age are hypothesized to influence neural response during the delay discounting task, it would seem that age groups would have to be matched on AUDIT scores in Aim 1.
- It is unfortunate that the interaction of age and drinking behavior could not also be studied in the adolescent group, although recruitment and testing of an additional 20 participants may not be feasible.

4. Training Potential:

Strengths

- Recommendation letters unanimously endorsed the strong training potential of the applicant
- The applicant has made good progress in transitioning to human neuroscience research, learning the behavioral tasks, and since the original application, neuroimaging training.
- Dr. Boettinger's lab and the Bowles Center provide excellent fMRI, cognitive neuroscience and alcohol training
- The decision to postpone extensive co-occurring training in structural MRI and DTI and make it a future direction increases the likelihood of in-depth training and mastery in fMRI

Weaknesses

- None noted

5. Institutional Environment & Commitment to Training:

Strengths

- Substantial commitment to training and research training opportunities in alcohol, neuroimaging, neurodevelopment, and the responsible conduct of research are provided by the faculty and activities of the Bowles Center for Alcohol Studies, the Developmental Neuroimaging Core of the UNC Medical School, the Behavioral Neuroscience Program and the Department of Psychology.

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Appropriate safeguards to exclude vulnerable persons from fMRI and to protect participant confidentiality

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

C1A - Children and Adults, Acceptable

- Nearly equal number of males and females
- Minority inclusion in proportion to their representation in the surround locale in NC. 11-42% African-American, 3-12.5% Hispanic, 4.5-7% Asian American, and less than 1% Native American and Pacific Islander. Plan in place to support minority recruitment.
- Children 18 years of age and older will be included; younger aged children are still showing large developmental changes in the frontal lobes and appropriately excluded from this training study

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The revised application was responsive to concerns raised in the previous review.
- A senior alcohol researcher was added to the application as a co-sponsor
- Supplemental mentoring will be provided by the applicant's dissertation committee which has expertise in alcohol studies, neuroimaging, neurodevelopmental disorders, and the neurobiology of learning and addiction.
- Coursework added in human brain development
- The research training plan was streamlined to focus on fMRI and the second imaging session was eliminated

- Age groups now defined based on preliminary behavioral data
- DTI and structural MRI data will still be collected, but their analysis will be pursued as a future research direction
- It was clarified that nondrinkers will be excluded

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- formal course work, seminars, CITI training, continuing education, discussions with sponsor and other faculty

Comments on Subject Matter (Required):

- Research ethics including authorship, animal and human subjects, IRB, scientific honesty; training in HIPPA regulations and confidentiality, CITI program

Comments on Faculty Participation (Required):

- The primary sponsor and other faculty at the Bowles Center are involved in continuing education

Comments on Duration (Required):

- Prior and currently ongoing research ethics course work
- seminars, continuing education, and faculty discussion for the duration of the proposal

Comments on Frequency (Required):

- Yearly, but specific frequency of seminars, continuing education, and faculty discussion not clear

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Fellowship Applicant: 2

Sponsors, Collaborators, and Consultants: 2

Research Training Plan: 2

Training Potential: 1

Institutional Environment & Commitment to Training: 1

Overall Impact/Merit

This is a revised 3-year NRSA application from an excellent candidate with strong training potential. The research plan now has a stronger focus on 1 neuroimaging modality and will train the applicant in fMRI data acquisition, processing, and analyses as well as in clinical research methodology. While the sponsor is relatively junior, she has done good work and appears to be able to provide the applicant with the appropriately focused research experience at this stage in his career. The applicant will benefit directly from two other postdoctoral fellows in the lab and Dr. Crews as co-sponsor. The research environment is excellent.

1. Fellowship Applicant:

Strengths

- The applicant is an A/B student with strong reference letters. He has a broad neuroscience background and transitions into human work with this application.
- The applicant added appropriate course work and has manuscripts in preparation/submission.

Weaknesses

- None noted

2. Sponsors, Collaborators, and Consultants:

Strengths

- Dr. Boettiger has greatest expertise in fMRI of delayed discounting and impulsivity and, although in the very early stages of her own scientific independence, is well-suited to sponsor this predoctoral fellow in her area of expertise. She also sponsors two post doctoral fellows.
- Dr. Fulton Crews, a co-sponsor, serves both as the candidate's scientific research and career mentor and has a history in mentoring strong future researchers in the alcohol field. His group has recently added human neuroimaging to its armamentarium and he should be able to support the applicant in this respect.

Weaknesses

- The relative juniority of the sponsor.

3. Research Training Plan:

Strengths

- Single focus on fMRI. Appropriate, given the complexities of the originally proposed structural and DTI methodologies and the relative lack of corresponding expertise among the sponsors.
- The research rationale has been strengthened and clarified. Groups have been defined better, with greater potential for detection of actual group differences. But even if no group differences will be forthcoming (which is not likely given some preliminary results), applicant proposes to pool groups and use age as a continuous factor in the analyses.
- Patient screening and assessment procedures are strong and thorough and the candidate has great opportunity to learn the tricks of the trade through being involved in all aspects of the clinical research.
- Assurance of funding by sponsor.

Weaknesses

- Moderate alcohol and nicotine use is allowed. It is unclear what that means, it should be quantitated and considered to be included as covariate(s) in the analyses.

4. Training Potential:

Strengths

- The applicant has broad background training in the neurosciences and is likely to gain much clinical research knowledge from the proposed research work in the stellar environment at UNC.
- DTI has been appropriately dropped from the main research plan and so has training in sMRI. Therefore, the applicant can better focus on one MR modality at this time in his career.

Weaknesses

- none

5. Institutional Environment & Commitment to Training:

Strengths

- The research environment at the Bowles Center at UNC is outstanding.
- The applicant even proposes to take advantage of course at nearby Duke.

Weaknesses

- none.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Sufficiently described and appropriate training obtained and proposed.

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

C1A - Children and Adults, Acceptable

- children between 18 and 21 will be studied as part of the adolescent cell

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- Applicant was responsive and the application improved significantly

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- fine

Comments on Subject Matter (Required):

- fine

Comments on Faculty Participation (Required):

- fine

Comments on Duration (Required):

- fine

Comments on Frequency (Required):

- fine

Budget and Period of Support:

Recommend as Requested

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

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.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. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Neuroscience Review Subcommittee National Institute on Alcohol Abuse and Alcoholism Initial Review Group NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

AA-4 1

March 08, 2011 - March 09, 2011

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