SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **06/30/2015**

Application Number: **1 F32 DA041157-01**

Smith, Christopher Thomas PHD
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Review Group: **ZRG1 F02A-J (20)**
Center for Scientific Review Special Emphasis Panel
Fellowships: Behavioral Neuroscience

Meeting Date: **06/18/2015**
Council: **OCT 2015** ***PCC:*** **CE/DCK**
Requested Start:

Project Title: **Linking Temporal Differences in d-Amphetamine Subjective Effects to DRD2 and DAT**

Requested: **3 years**

Sponsor: **Zald, David H**
Department: **Psychology**
Organization: **VANDERBILT UNIVERSITY**
City, State: **NASHVILLE TENNESSEE**

SRG Action: **Impact Score: 23 Percentile: 7**
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: **1A-Both Children and Adults, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

1F32DA041157-01 Smith, Christopher

RESUME AND SUMMARY OF DISCUSSION: This is a postdoctoral fellowship application from Dr. Christopher Smith who proposes to use PET measures of dopamine signaling, at the level of D2 receptors and dopamine transporters, to identify specific sites in the brain that track with faster and more positive subjective responses to acute oral d-amphetamine. The applicant has four publications and very strong letters of support that indicate he has a promising career in research ahead of him. The sponsor, Dr. David Zald, has expertise that fits well with the work proposed and the applicant's career goals. He is productive, well funded, and has a track record of training students and fellows. A minority of the reviewers thought that a sponsor with expertise in PET, beyond that of Dr. Zald, would strengthen the application but most felt Dr. Zald was a perfect fit. The additional consultants, Drs. Harriet de Wit, Abraham Palmer, Ronald Cowan, and Randy Blakely, also add significant strength to the application, particularly in terms of complimentary expertise. The research plan will provide excellent training opportunities, in terms of both bench skills and conceptual skills. The proposal was well written and clearly articulated. Some concern was raised about whether there will be enough dispersion in the principal outcome measures to link subjective responses effectively with differences observed. Additionally, there was concern that the inclusion of an older age group might make the results difficult to interpret. Overall, the training potential was seen as outstanding.

DESCRIPTION (provided by applicant): While the speed of delivery of drugs of abuse to the brain are thought to underlie their addictive potential, no research has focused on individual differences in speed of psychostimulant-induced high and liking and whether such differences are reflected at the level of the brain, personality, or genetics. Yet, preliminary data from our research group indicates there are dramatic differences in the temporal profile of subjective responses to oral d-amphetamine. The research proposed in this fellowship will use Positron Emission Tomography (PET) to assess multiple aspects of dopamine system function (striatal and extrastriatal D2-like binding potential, dopamine transporter levels, and d-amphetamine-induced dopamine release) and relate these PET measures to differences in positive subjective responses (drug high and liking) to d-amphetamine, with a particular emphasis on the timing of peak positive subjective drug effects. Furthermore, the proposed research will assess how individual differences in dopamine system function and the positive subjective effects of d-amphetamine vary with personality traits and genetic polymorphisms in healthy adults. Specifically, we will investigate the role of commonly studied polymorphisms in dopamine-related genes as well as a signal nucleotide polymorphism in the cadherin 13 gene previously found to be associated with the positive subjective effects of d-amphetamine in a genome wide association study. The goal of this research plan is to better understand individual differences that confer potential risk for psychostimulant addiction including a fast rise in dopamine and increased subjective high/liking after drug intake. The applicant's long-term goals are to identify how differences in dopamine system function relate to addiction risk at the level of behavioral endophenotypes including subjective drug high/liking time to peak, novelty seeking, and impulsivity (including steep temporal discounting). This fellowship will help the applicant develop expertise in measuring variation in the dopamine system (through PET and genetic approaches) and prepare him for a productive career as an independent investigator of dopamine's role in addiction risk, externalizing behaviors, and other traits often associated with drug addiction.

PUBLIC HEALTH RELEVANCE: Differences in the speed of delivery of drugs of abuse as well as the subjective high they produce are believed to relate to their addiction potential. This research fellowship will investigate whether observed differences in the timing of subjective psychostimulant effects are related to measurable differences in the functioning of the neurotransmitter dopamine, personality traits, and genetics. By understanding how these factors affect individual differences in drug responsivity we hope to identify potential biological and behavioral markers of psychostimulant addiction risk.

CRITIQUE 1

Fellowship Applicant: 2
Sponsors, Collaborators, and Consultants: 2
Research Training Plan: 4
Training Potential: 3
Institutional Environment & Commitment to Training: 1

Overall Impact/Merit: This is a new application for 2 years of postdoctoral support to carry out studies designed to link temporal differences in d-amphetamine subjective effects to DRD2, DAT and DA release measured by means of PET and neuron-specific ligands and amphetamine challenge in humans. This is a nicely written application that comes from a promising young scientist with strong academic credentials and letters of support who has already begun making contributions to the scientific record. While the applicant's multidisciplinary approach (both as a predoctoral fellow and in the present application) is laudatory, there is the risk of overextension and the failure to appreciate limits of individual techniques. The primary mentor, Dr. Zald, is an accomplished psychologist who appears well suited to oversee the proposed research and training, although his primary area of expertise is not PET imaging or image analysis (said to be primary areas of training). Along with a primary sponsor, the applicant has assembled a large mentoring team (Drs. Cowan, Blakely, de Wit and Palmer, Swift-Scanlan) all of whom have the potential to contribute to the applicant's planned research and training. The research plan is nicely articulated and based upon promising pilot data that confirm recent work published by de Wit (significant individual variability in subjective response to amphetamine) and is coupled to provocative pilot PET data. Concerns with the proposed research plan center on three principal issues: 1) unclear if PET measures of DAT, DRD2, and DA release will have sufficient dispersion to permit discernment of significant (vs. spurious) correlations; 2) sample size, demographics and composition; 3) drug screens and 4) no apparent intent to include physiological responses to amphetamine. Training potential is deemed high as the applicant will acquire research skills in PET imaging and image analysis (said to be major focus) and complement these with increased experience with collecting measures of human reward, personality, and genetic markers. Vanderbilt will provide an excellent environment for the conduct of the proposed research and training.

1. Fellowship Applicant:

Strengths

- Mostly As, few Bs and one C+ as undergraduate at Furman University; Honors and Pass grades as predoctoral fellow at University of North Carolina
- 4 publications, 2 papers in review or revision, 2 papers in preparation
- Very strong letters of support
- Various academic and professional honors
- Well written, nicely organized application
- Comes across as gifted, scholarly young scientist

Weaknesses

- May have tendency toward overextension

2. Sponsors, Collaborators, and Consultants:

Strengths

- The primary sponsor, Dr. Zald, is an academic psychologist who directs the Affective Neuroscience Laboratory at Vanderbilt University and has developed imaging expertise. Given his background and training, he is well suited to oversee some of the proposed research and training (see below). Dr. Zald has previously mentored 7 postdoctoral scientists.
- The rest of the large mentoring team consists of an accomplished group of scientists (Drs. Cowan, Blakely, de Wit and Palmer) each of whom has expressed willingness to assist the applicant in his endeavors.
- The primary mentor has the requisite support to fund the proposed studies; letters of support are in place.

Weaknesses

- Primary mentor's principal area of expertise is not PET imaging or image analysis – said to be major focus of applicant's training

3. Research Training Plan:

Strengths

- Proposed studies are based on provocative pilot data pointing to individual differences in amphetamine response.
- Understanding biological basis of individual differences in amphetamine response is important as it may shed light on risk for stimulant addiction
- State-of-the-art PET measures of in vivo "DA signaling".
- Power analysis for behavioral outcome measures included.
- Multidisciplinary approach (PET imaging, drug challenge, personality measures, PK analysis, genetics).

Weaknesses

- PET outcome measures not likely to have sufficient dispersion to allow "linking" of temporal differences in subjective response to d-amphetamine to DAT, DRD2 levels and DA release index. This problem will be particularly acute in brain regions with low signal-to-noise properties (e.g., sgACC, where signal-to-noise likely to be less than 1.5 to one).
- For "DA release" measure, test-retest variability of ^{18}Fallypride were not provided. It could cloud true individual DA release variability and complicate the analysis. Not clear that sample size will be large enough to attain study objective. Changes in ^{18}Fallypride binding after amphetamine release [(%ΔBPnd)) are typically rather small (10-15%). Amounts of DA release (-%ΔBPnd) in ROIs (striatum, amygdala, midbrain, insula and temporal cortex) were not provided.
- Cohort to be used is not sufficiently well detailed. The application states: "the additional 60 subjects we will recruit here added to current data will result in a minimum of 15 subjects in our smallest DEQ_{H+L} group (Early Peak Responders)." However, the total number of subjects in the cohort is never specifically indicated. It is not clear if the demographics of the old and new groups are the same. Age ranges ages (20-30 and 50-60) may not be ideal.
- Not clear that sample sizes are sufficiently large to allow for control for potential pharmacokinetic differences and other factors that may influence DA signaling markers (age, gender, etc.), as planned. Statistical consultation is advisable.
- Drug screens planned for only one visit even though PET scans will require separate visits

- No apparent plan to also collect physiological data after amphetamine challenge. Such data could shed light on basis for observed individual response variability to amphetamine.

4. Training Potential:

Strengths

- Training activity will focus on expanding research skills, with a particular emphasis on developing expertise in PET imaging (including kinetic modeling) to better understand the role of DA in human reward, motivation, and decision making as it relates to drug addiction.
- Training plan includes didactic coursework and workshops, learning of new skills (see above), training in oral and written communications and presentation of data at journal clubs and professional meetings.
- Teaching skills will also be developed

Weaknesses

- To optimize training potential, a sponsor with primary expertise in PET imaging and imaging data analysis would be ideal (given candidate's stated training objectives).
- Reference region methods may not be ideal
- Not clear exactly how the behavioral and genetic data to be obtained from the U of Chicago data set will be used and incorporated into present proposal
- Statistical consultant might be considered

5. Institutional Environment & Commitment to Training:

Strengths

- Vanderbilt provides an excellent environment for the conduct of the planned research and training.

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21:
- Appropriate

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Acceptable

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- Formal courses and online training, meetings with sponsor

Comments on Subject Matter (Required):

- Specified

Comments on Faculty Participation (Required):

- Faculty participates

Comments on Duration (Required):

- Throughout fellowship period

Comments on Frequency (Required):

- Weekly

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

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

Overall Impact/Merit: The applicant proposes to study dopamine system function (speed of drug delivery) and positive subjective responses (subjective high – low peak, high peak, nonresponders) as a function of personality traits and genetics (cadherin 13 gene). This line of research is intended to inform individual differences in addiction, novelty seeking, impulsivity, and externalizing behaviors. This postdoctoral applicant seeks training in Positron Emission Tomography (PET) imaging, PET data analysis (kinetic modeling of PET data), SEM, and genetic analysis. The applicant outlines training for three years. The team of mentors is stellar, each contributing different areas of expertise (PET, genetics, d-amphetamine). The study proposes to examine dopamine signaling (via PET) pre and post dAMPH administration and relate it with subjective effects as well as genes (cadherin 13 gene) and personality measures. Hypotheses outlined are clear, operational, and plausible (grounded in preliminary study findings). The PET sample will involve 30 20-30 year olds and 30 50-60 year olds recruited as part of sponsor's R01 and they will be imaged twice (placebo and drug conditions). Plasma samples will be collected every 30 minutes for 2 hours and then at hours 3 and 4.5 to assess drug levels and absorption.

1. Fellowship Applicant:

Strengths

- Received PhD from Univ. of North Carolina, Chapel Hill in 2014 in Neurobiology. Has worked with behavioral data and dAMPH. Now, wants to connect dAMPH responsivity to genetic data and dopamine system brain data.
- Applicant has four published papers (3 first authored) in top tier journals, another in revision, and one under review.
- All letters overwhelmingly praise the applicant, speaking to his logic, hard work, promising career, and so forth.

Weaknesses

- Undergraduate grades were mostly As, some Bs, one C+. Graduate graders were evenly high pass and pass.

2. Sponsors, Collaborators, and Consultants:

Strengths

- The letters written are glowing and convey a strong history of collaboration for this team which includes Drs. David Zald and Ronald Cowan at Vanderbilt and Harriet de Wit and Abraham Palmer at the University of Chicago.
- Generic data will be shared by Drs. de Wit and Palmer.
- Dr. Zald is a great fit to serve as a mentor for the applicant given expertise in neuropharmacological substrates, neuropharmacology, affective neuroscience, and personality. He has mentored numerous pre- and postdoctoral students and early career investigators in their training. He is prolific and has several externally funded grants as PI that span the time of the proposed fellowship.
- Similarly Dr. de Wit has extensive expertise in examining the psychological, behavioral, and biological determinants of drug abuse (expert in dAMPH), has mentored numerous students and junior faculty members, has an extensive publication record, and impressive external grant funding record.
- Dr. Palmer is an expert in genetic variation in behavior, among animals (rats and mice) and with humans (as it relates to dAMPH). Dr. Palmer has significant external funding as a PI.
- Dr. Cowan is expert in reward systems – particularly dopamine - as they relate to drug dependence and will mentor the applicant on imaging analyses and interpretation.
- Dr. Blakely is expert in neurotransmitter signaling.
- The applicant has a team of stellar mentors and consultants who each contribute needed expertise for this fellowship.

Weaknesses

- Geographical distance between applicant and U. Chicago colleagues.

3. Research Training Plan:

Strengths

- The study design is robust with both drug and placebo conditions for each person (N=60). Study contains a placebo comparison condition and plasma blood levels to assess absorption. But, the applicant does not talk about the possible attrition between visits.

- Questionnaire measures proposed are validated to assess sensation seeking, impulsivity, and so forth. But, additional personality measures may bolster this study (e.g., Big Five).
- The use of multiple biomarkers (PET, genes, blood, drug) and psychological measures is a strengths. There are some neuropsychological tasks that could be used to assess impulsivity as well.
- The genetic sample is large (n=381).

Weaknesses

- The study only addresses a psychostimulant. Inclusion of other drugs (non-stimulants) as a comparison would aid in generalizing the hypothesis for addition to other classes of drugs.
- The logic for including 50-60 year olds is not clear (just that this is part of the sponsor's R01 recruitment). And it is not clear how this sample aligns with the U Chicago genetic sample (N=381).

4. Training Potential:

Strengths

- Training in PET image processing is underway. Further training includes kinetic modeling of PET data (via auditing lectures by Dr. Morris at Yale or workshops), reviewing articles (with Zald) written by Dr. Morris, SEM and Human Genetics courses at Vanderbilt, and Jackson Laboratory course on Genetics of Addiction.
- Will attend scientific meetings, provide talks at departmental or institute seminars, continues to mentor undergraduate students, and guest lecture.
- Timeline for three years is reasonable and sufficiently detailed. Over 70% of time will be allocated to research with some time devoted to grant writing, teaching, and conferences/ meetings/ workshops.
- Highly regarded description of the applicant by Zald "Christopher arrived at Vanderbilt with a strong knowledge base in issues related to reward, dopamine functions, hormones and genetics, and has rapidly expanded this base while pursuing the human and animal literatures on dopamine, psychostimulants, personality and possible individual differences in temporal dynamics."

Weaknesses

- It is not clear how much knowledge the applicant already has with genetics and genetic modeling. Some genetic experience is evident from doctoral work (more training is needed in genetics of addiction, however).
- No coursework is outlined related to PET.

5. Institutional Environment & Commitment to Training:

Strengths

- Affective Neuroscience Lab in the Department of Psychological Sciences and the Vanderbilt Vision Research Center offers computing and software resources and support staff including engineers and programmers.
- Department offers weekly seminars, colloquia, and monthly external speaker series.
- Vanderbilt University Medical Center has a state-of-the-art PET Center and Vanderbilt University Institute of Imaging Science has two 3T and one 7T Philips scanners as well as dedicated space for other data collection (e.g., interview rooms).

- Vanderbilt Technologies for Advanced Genomics (VANTAGE) specializing in DNA extraction, banking, and variation analyses.
- Blood panels and EKG data collection are supported by Vanderbilt Institute for Clinical and Translational Research (VICTR).
- Additional supports include Vanderbilt Center for Cognitive and Integrative Neuroscience (CCIN) and Vanderbilt Brain Institute (VBI) and several postdoctoral support offices.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Total of 60 participants (30 ages 20-30 and 30 ages 50-60). The applicant thoroughly discussed risks, discomforts, and protocols to minimize these and to maximize quality control.

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

Acceptable

- Independent safety monitor will be assigned to this study and meetings will be held annually and following any adverse event

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- Distribution by sex (half female) and race/ethnicity are proportionate to the context. PET is not appropriate for children.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Comments on Format (Required):

- All personnel will complete CITI training; applicant will maintain HIPAA and CITI certification and complete the NIH Online Course on human subjects protection as required for obtaining federal research funds; weekly lab meeting discussions.

Comments on Subject Matter (Required):

- Researchers' responsibilities, subject confidentiality, data handling, conflict of interest, and noncompliance reporting.
- No mention of MR or PET specific training.

Comments on Faculty Participation (Required):

- Only discussed Dr. Zald discussions during lab meetings.

Comments on Duration (Required):

- Not specified.

Comments on Frequency (Required):

- Ranges from weekly to annually.

Resource Sharing Plans:

Acceptable

- Will share data upon request and/ or with data-sharing agreement that safeguards participants.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

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

Overall Impact/Merit: Dr. Smith is a new postdoc in Dr. Zald's lab and seems to have hit the ground running thus making the training potential for this current proposal very high. Dr Smith got his PhD in neurobiology at UNC in 2014 and has experience with delay discounting, behavioral, genetic and epigenetic methods, and some PET methodology. His letters are outstanding and he has been very productive to date, including a paper under revision with Dr. Zald already. To date his work focused on molecular neuroscience and neuropharmacology. In his postdoc, and especially in this proposal he will gain training in cognitive neuroscience, affective science, neuroimaging methods and expand his knowledge of PET methods considerably. The sponsor and whole advisory team are outstanding and the research environment is exceptional at all levels.

The research project has several notable strengths including, examination across multiple levels of analysis (behavioral, personality, neural, and genetic), strong preliminary data much of which Dr. Smith has done in a short time at Vanderbilt. The project is highly significant and extremely innovative. I have a couple of minor critiques. Frist, it would be helpful to have a bit more discussion of the implications of this work for the scientific community and what the translational significance would be. Second, having the two age groups (from the larger parent grant) may introduce some important issues that were not discussed in background. Would it be possible to just focus on one of the age groups to avoid any problems associated with reduced DA in the older participants?

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

Inclusion of Women, Minorities and Children:

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

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Acceptable

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- Online, formal courses

Comments on Subject Matter (Required):

- Human subject protection, and research ethics

Comments on Faculty Participation (Required):

- Weekly meetings with Dr. Zald

Comments on Duration (Required):

- Duration of the award period, 3 years

Comments on Frequency (Required):

- Weekly with sponsor, and yearly renewals

Select Agents:

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

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-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

Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
Fellowships: Behavioral Neuroscience
ZRG1 F02A-J (20) L
June 18, 2015 - June 19, 2015

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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.

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