November 2, 2009

Institutional Review Board

Texas State University – San Marcos

Re: IRB Application 2009U5299

Dear Committee Members,

Thank you for your time and care in reviewing my submission entitled: “Stress-related alterations in impulsivity and risk-taking among young adult tobacco users, tobacco and marijuana users and non-users”. In order to address the concerns of the reviewers, I have made changes to the recruitment flyer, consent form and other aspects of the study, as described in the synopsis. I have included the reviewer’s comments in italics and my replies, along with an explanation of the changes made to the relevant procedures or documents below. Please note that I appeared to receive three sets of comments about the submission (one on 10/15/2009 and 2 on 10/21/2009, separated by 10 minutes). The two on 10/21 appeared to be from the same person and the first set was redundant with the second, so I am only addressing the second set from 10/21 here.

**Reviewer #1**

1. *Please reword the last sentence in the “Confidentiality” section so that it makes sense: “This does not prevent you from voluntarily releasing information about themselves or their involvement in the study with written consent.”*

**PI Reply:** Per the reviewer’s request, this section was reworded so that it made better sense.

1. *Please submit for review any questionnaires used in the study.*

**PI Reply:** All self-report questionnaires used and the Timeline Follow-back Interview (assessing substance use), which is given by the investigator, are included in this revision submission.

1. *What, if any, measures will be taken to insure that complete confidentiality will be undertaken by your student aids other than completion of the CITI course? I’m concerned due to the fact that some participants will be exposing their illegal behavior/habits to fellow students who may lack the level of maturity of the PI.*

**PI Reply:** I am sensitive to this concern as well, as marijuana use is illegal behavior by all participants. The three identified student research assistants will be taking part in weekly meetings with the PI in order to receive training in both study procedures and the responsible conduct of research (e.g., privacy, confidentiality, data integrity and protection, etc.) based off of readings and materials the PI obtained while taking a course in the responsible conduct of research during his Postdoctoral Fellowship at the Yale University School of Medicine. Furthermore, all student research assistants will serve a “probationary” period of at least 60 days where I will continually assess their fitness to serve as research assistants. During this time, they will not take part in the assessment of participant marijuana use, and they will be blind to the participant’s use status (please note that they will not be blind to participant tobacco use).

Reviewer #2

1. *The recruitment flyer does not say anything about recruiting marijuana users, it only says \'a study of stress response, impulsivity and risk taking in users of tobacco and nonusers of tobacco\'*

**PI Reply:** The recruitment advertisement has been changed to include “users of marijuana and tobacco” among those sought for participation.

1. *Legal protection of participants especially marijuana users must be secured by assuring anonymity and confidentiality. Due to the sensitive nature of the study, the investigators must obtain the CoC from NIH for this study.*

**PI Reply:** I agree wholeheartedly that the CoC is a necessary protection for research participants. I assume, however, that the reviewer is stating that the CoC must be obtained before IRB approval will be granted (not that s/he agrees with my intention to seek a CoC). Unfortunately, the National Institute on Drug Abuse (the relevant NIH division for this submission) requires that IRB approval be granted prior to submission of a request for a CoC. Reviewers are referred to the NIDA webpages on the CoC (<http://grants.nih.gov/grants/policy/coc/index.htm>) and FAQs on the CoC (<http://grants.nih.gov/grants/policy/coc/faqs.htm>) for more information on this. Thus, I need approval before I can submit the necessary paperwork for a CoC.

1. *To assure further confidentiality, I would suggest the investigators develop and something similar to non-disclosure document, that will be signed by the investigator and the participants. This will protect (to certain degree) disclosure of illicit behavior of some participants by others in the study if they are exposed. This is especially important because, the NIH CoC only protects the participant from disclose by the PI but does not take into consideration the co-participants. I suggest such a non-disclosure certificate be included with the consent form. This may not have any legal binding, but at least makes the participants aware that they cannot disclose such information.*

**PI Reply:** I was somewhat confused by this concern, and I believe it is the result of a misunderstanding about the nature of the research. The participants in the study will take part in all procedures individually; in other words, each participant will meet only with the PI and/or his student research assistants. No other participants will be present. Thus, the only individuals who could disclose the participant’s drug use status (or other sensitive information) are the PI or the student research assistants. Reviewer #1 notes concerns about the student research assistants (addressed above), but should be no concerns about others gaining knowledge about participants because all participants complete the research individually. Furthermore, the consent and recruitment flyer are worded to ensure that no one knows the substance use status of participants, since non-users are included in the research.

1. *I would certainly like to see the questionnaire.*

**PI Reply:** As mentioned above, all self-report questionnaires and the Timeline Follow-back interview are included in this resubmission.

Thank you again for your time and concern about my project.

Best wishes,

Ty Schepis, Ph.D.

Assistant Professor of Psychology