UNIVERSITY OF HOUSTON
Division of Research
Institutional Review Board Application

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Institutional Review Board Application ID :	13547-EX - (3356)
Title :	Depression among Aging Mexican American Heroin Injectors

Approval details for the Application Id: 3356

	Decision	Approver Name	Date	Comment
PI signature	Approved	Villarreal, Yolanda Ms.	03/27/2014	
DOR signature	Approved	Admin, IRB	05/28/2014	

Application Data for Application ID: 3356

Title	Depression among Aging Mexican American Heroin Injectors
Application Type	New
Review Type	Exempt
Expedite Code	Not Applicable
Exemption Code	4: Research involving the collection/study of data
Research Reason	Unfunded Research,Doctoral Dissertation

Investigator Data for Application ID: 3356

PI Name	Is Pricipal?	Is Co-Investigator?	Is External?	Other Personnel Type?	Is Student?	Faculty Sponsor Name
Villarreal, Yolanda Ms.	Yes		No		Yes	Torres-Hostos, Luis Dr.
Torres-Hostos, Luis Dr.			No	Thesis Committe Member	No	Not Applicable
Bordnick, Patrick Dr.			No	Thesis Committe Member	No	Not Applicable
Ren, Yi Miss			No	Other Research Personnel	No	Not Applicable

Project Review Summary Data for Application ID: 3356

Question	Answer
4) State the specific research hypotheses or questions to be addressed in this study	This research study, proposes to analyze data that has already been collected from a project now in its final year (UH IRB Number 07298-01; Project ID 104319). The original study focuses on examining the life course development, determining social conditions, and health consequences of long-term injection heroin use in aging Mexican American men. The focus of the proposed research project is to study the protective and risk factors for depression among this population. Specifically, the proposed research will examine the micro individual variables of stress and incarceration history and the macro variables of four cultural values (i.e. familismo, machismo, fatalismo, personalismo) and their impact on depression status. Given the secondary data analysis nature of this research we are submitting this protocol as Exempt--Category 4.
5) What is the importance/significance of the knowledge that may result?	Understanding determinants, predictors, and mental health consequences of injection heroin use in this population can allow us to develop appropriate prevention and treatment interventions that are culturally grounded.
6) Type of Subject Population (check all that are appropriate)	Adults,Elderly (65yrs and above)
6.01) Expected maximum number of participants	227
6.02) Age of proposed subject(s) (check all that apply)	Adults (18yrs-64yrs),Elderly Adults (65yrs and above)
	As per original protocol. Mexican American men (by self-identification); 45 years old and older; history of lifetime prevalence of chronic, long-term injection heroin use; and fall into one of our three groups: former injection

6.03) Inclusion Criteria:	heroin users currently enrolled in a methadone maintenance treatment program; current users who are not in treatment and have been injecting regularly for the past year; and former users who have not injected heroin in the past three years and are not in treatment currently.
6.04) Exclusion Criteria:	As per original protocol. Research was voluntary, so participants who refused to participate were not enrolled. Additionally, no individuals with developmental delays or severe and persistent mental illness in an active stage were included in the study.
6.05) Justification:	As stated in the original application, justification for the specific ethnic and age cutoff were twofold. Health risks confronted by heroin users include homicide and HIV/AIDS, and these are more prevalent causes of death for Hispanic males than for non-Hispanic White males. Additionally, an age threshhold of 45+ allows for comparisons with the Center for Disease Control and Prevention's National Center for Health Statistics data, which groups adults into 45-64 and 65 and older.
6.06) Determination:	See original approved application.
7) If this study proposes to include children, this inclusion must meet one of the following criterion for risk/benefits assessment according to the federal regulations (45 CFR 46, subpart D). Check the appropriate box:	
8) If the research involves any of the following, check all that are appropriate:	Study of Existing Data,Data Analyses Only
9) Location(s) of Research Activities:	UH campus
10) Informed Consent of Subjects: Your study protocol must clearly address one of the following areas:	No Informed Consent. You may request a waiver of informed consent with Appendix B - Request for Waiver/Modification of Informed Consent. If applicable, a copy of the modified consent document is required. ATTACH APPENDIX B.

Research Protocol Data for Application ID: 3356

Question	Answer
	Data analyses only. All data collection has been completed according to the approved IRB protocol (07298-01). Two different papers will result from this analysis. First, using bivariate analyses the relationship between depression and the sociodemographic variables will be examined. These bivariate analyses will identify the final sociodemographic control variables that are associated with depression. Sociodemographic variables that are theoretically considered to be confounders will be distinguished from those that are hypothesized to be theoretically meaningful predictors of depression.The three moderating relationships; 1) Family drug use moderating the relationship between familismo and depression, 2) Frequency of drug using members in networks moderating the relationship between personalismo and depression, and 3) religion moderating the relationship between fatalism and depression will be assessed by examining the interaction variable between the predictor and the moderator. Before examining the interaction variable the predictor and moderator variables must be centered (subtract the mean) in order to accurately interpret their effect on the outcome variable; depression. Once the variables have been centered the

11) Describe the research study design. (Describe the research methods to be employed and the variables to be studied. Include a description of the data collection techniques and/or the statistical methods to be employed.)	interaction effect can be computed by multiplying the predictor by the moderating variable. Each relationship's impact (i.e. predictor independently, moderator independently, and interaction effect) will be tested against the outcome variable at the bivariate analysis level using chi-squares. The relationship between depression and acculturation and machismo (non-moderated variables) at the bivariate level also using a chi-square test will then be assessed. All statistically significant relationships will be entered into a multiple logistic regression model in order to control for confounding relationships and to identify which are independently associated with depression. The logistic regression test is appropriate given the dichotomous nature of the dependent variable. Adjusted Odds Ratios (AOR) will be reported for each significant relationship. For the second analysis, bivariate analyses will be used to examine the relationship between depression and incarceration and stressful life events. The stressful life events scale is scored by adding the sum of all items (1 to 12) thus at the bivariate level I will conduct a bivariate logistic regression to assess for significant relationships between this variable and depression. The bivariate logistic regression is an appropriate method of analysis for these variables given that it will provide better information than a simple independent t-test. Incarceration will be coded as an ordinal variable and the chi-square test will be used to assess for associations at the bivariate level. Finally, multiple logistic regression will then test whether depression is independently related to the potential predictors. Adjusted Odds Ratios (AOR) will be reported for each significant relationship. The analyses for all Aims will be conducted using SPSS 20.
12) Describe each task subjects will be asked to perform.	Data analyses only. All data collection has been completed according to the approved IRB protocol (07298-01).
13) Describe how potential subjects will be identified and recruited? (Attach a script or outline of all information that will be provided to potential subjects. Include a copy of all written solicitation, recruitment ad, and/or outline for oral presentation.)	Data analyses only. All data collection has been completed according to the approved IRB protocol (07298-01).
14) Describe the process for obtaining informed consent and/or assent. How will investigators ensure that each subjects participation will be voluntary (i.e., free of direct or implied coercion)?	Data analyses only. All data collection has been completed according to the approved IRB protocol (07298-01). Original informed consent was obtained and is on file as part of the original application.
15) Briefly describe each measurement instrument to be used in this study (e.g., questionnaires, surveys, tests, interview questions, observational procedures, or other instruments) AND attach to the application a copy of each (appropriately labeled and collated). If any are omitted, please explain.	Please refer to original IRB protocol (07298-01).
16) Describe the setting and mode for administering any materials listed in question 15 (e.g., telephone, one-on-one, group). Include the duration, intervals of administration, and amount of time required for each survey/procedure. Also describe how you plan to maintain privacy and confidentiality during the administration.	Please refer to original IRB protocol (07298-01). Data analyses will take place in the UH Center for Drug and Social Policy Research, located in the Graduate College of Social Work.

17) Approximately how much time will be required of each subject? Provide both a total time commitment as well as a time commitment for each visit/session.	N/A No additional interveiws will be conducted
18) Will Subjects experience any possible risks involved with participation in this project?	
18.01) Risk of Physical Discomfort or Harm	No:
18.02) Risk of Psychological Harm (including stress/discomfort)	No:
18.03) Risk of Legal Actions (such as criminal prosecution or civil sanctions)	No:
18.04) Risk of Harm to Social Status (such as loss of friendship)	No:
18.05) Risk of Harm to Employment Status	No:
18.06) Other Risks	No:
19) Does the research involve any of these possible risks or harms to subjects? Check all that apply.	:N/A Data analysis only
20) What benefits, if any, can the subject expect from their participation?	N/A Data analysis only
21) What inducements or rewards (e.g., financial compensation, extra credit, and other incentives), if any, will be offered to potential subjects for their participation?	N/A. Data analysis only

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Question	Answer
22) Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, patient or student ID numbers, etc.?	No:
23) Will you retain a link between study code numbers and direct identifiers after the data collection is complete?	No:
24) Will anyone outside the research team have access to the links or identifiers?	No:
25) Where, how long, and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept? In addition, describe what security provisions will be taken to protect these data (password protection, encryption, etc.). [Note: University of Houston policy on data retention requires that research data be maintained for a minimum of 3 years after completion of the project. All research data collected during this project is subject to the University of Houston data retention policy found at http://www.research.uh.edu/Home/Division-of-	Data will be kept as per all UH and federal regulations. Specifically, all physical data is locked in a file cabinet that is kept in a locked office (Room 303) at the Graduate College of Social Work which is located on the University of Houston property. All electronic data is de identified and kept on a secure computer that is kept in a locked office. In addition, since the study was funded by NIDA, data must be archived following completion of all data analyses as per NIH regulations. Furthermore, all of the individuals tied to this application have completed the University of Houston's Human Subjects training.

Research/Research-Services/Research-Policies/Access-to-and-Retention-of-Research-Data.aspx]	

Appendix B Data for Application ID: 3356

Question	Answer
27) Does the proposed research, in its entirety, involve greater than minimal risk? (Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research which are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.) (If yes, your study is ineligible for waiver of informed consent under 45 CFR 46.116(d).)	No:
28) Could the proposed research be practically carried out without the waiver? (If yes, your study is ineligible for waiver of informed consent. OR If no, please explain)	No: :No: Only analysis and write up (publications) of collected data.
29) Will the requested waiver of informed consent affect the rights and welfare of the subjects? (If yes, your study is ineligible for waiver of informed consent. OR If no, please explain)	No: :No: Only analysis and write up (publications) of collected data.
30) If applicable, will pertinent information be provided to subjects later? (If yes, please explain OR If no, your study is ineligible for waiver of informed consent)	Yes: :Yes: N/A Study of Existing Data