PREVALENCE & CLINICAL COURSE OF DEPRESSION AMONG PATIENTS WITH HEART FAILURE, VA HSR&D, NURSING RESEARCH INITIATIVE # 05-209-3
VA FORM 10-21085a,b,c,d,e(NR)
OMB 2900-XXXX

I. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

The VA Greater Los Angeles Health Care System (VA GLAHS) is submitting this application to collect the necessary information for the research study, 'Prevalence and Clinical Course of Depression among Patients with Heart Failure'. This is a single-center, prospective longitudinal research study conducted among Veterans with heart failure (HF). The overall intent of this study is to identify the patterns of depression in HF over time and to understand the temporal relationship between clinical depression, alterations in physical functioning, and levels of circulating biochemical markers in HF in a highly vulnerable Veterans HF patient population. Knowledge regarding temporal relationships is vital to understanding how pathologic mechanisms of HF and depression interact and ultimately to designing optimal and complementary interventions for both conditions. The specific objectives of the study are identified in item #2. Legal authority for this data collection is found under 38 USC, Part I, Chapter 5, Section 527, which authorizes the collection of data that will allow measurement and evaluation of the Department of Veterans Affairs Programs, the goal of which is improved health care for veterans.

2. Indicate how, by whom, and for what purpose the information is to be used

a. The purpose of this information collection is to respond to the specific research objectives of the above-mentioned research study, which is to: 1) evaluate the prevalence of clinical depression (as measured by the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition [DSM-IV], the Diagnostic Interview and Structured Hamilton [DISH]) and depressive symptoms (as measured by Beck Depression Inventory [BDI]) among Veterans with HF during hospitalization and 2 weeks, 3 months, 6 months and 12 months post-discharge; 2) determine the temporal relationships of DSM-IV diagnosis of depression and physical functioning (measured by NYHA and Specific Activity Scale [SAS] functional class)[1] among Veterans with HF at different time points from hospitalization through outpatient care (within 3 days of hospital admission, discharge day, and then 2 weeks, 3 months, 6 months and 12 months post-discharge); and 3) determine the temporal relationships of DSM-IV diagnosis of depression (by DISH) and biochemical markers associated with HF and depression such as BNP and cytokines (i.e. TNF-α, IL-6 and IL-10), TNF-α/IL-10 ratio, and IL-6/ IL-10 ratio) among Veterans with HF at different time points from hospitalization through outpatient care (within 3 days of hospital admission, discharge day, and 2 weeks, 3 months, 6 months and 12 months post-discharge), and 4) determine the association of sociodemographic, clinical factors, comorbidities, physical functioning, biochemical markers, and social support factors to clinical depression among Veterans with HF. The long-term objectives of the study are to: 1) determine the influence of depression on physical functioning and inflammation over time in Veterans with HF, and 2) develop a practice model that would provide a systematic, timely, efficient and cost-effective evaluation of depression among Veterans with HF.

b. The information will be collected by the research RN and/or the principal investigator (PI). The research RN/PI will collect information via interviews using established questionnaires such as Mini-Mental State Exam (VA Form 10-21085a NR), Functional Class: NYHA and SAS (VA Form 10-21085b NR), DISH (VA Form 10-21085c NR), BDI (VA Form 10-21085d NR)and a Medical Outcomes Social Support Survey (VA Form 10-21085e NR). These questionnaires will be administered in a location that will provide adequate privacy for the respondent. In addition, the research team will observe strict confidentiality for the responses provided by the respondents. The research RN/PI will record information on respective paper questionnaire. Then, they will store the

collected information in a locked file cabinet and will enter the necessary data in an encrypted research computer. As indicated above, questionnaires will be administered at 6 different time points per respondent (or subject): 3 days after hospital admission, at hospital discharge, and at 2-weeks, 3-months, 6-months and 12 months post-hospital discharge.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

The collection of information via questionnaires will not involve automated, electronic, mechanical or other technological collection techniques. These questionnaires are not available in automated formats. Automating these set of research questionnaires (i.e. Mini-Mental State Exam [VA Form 10-21085a NR], Functional Class: NYHA/SAS [VA Form 10-21085b NR], DISH [VA Form 10-21085c NR], BDI [VA Form 10-21085d NR], and a Medical Outcomes Social Support Survey [VA Form 10-21085e NR]) is unlikely to lessen time burden for respondents for 2 reasons: 1) blood specimens will be collected at the same time these set of questionnaires will be administered; 2) the number of items for each questionnaires will not be reduced by automation. To reduce time burden for the respondents, the research team will offer the respondents a choice for the location of follow-up data collection (that includes collection of blood specimens and administration of research questionnaires), which will be in the hospital research clinic or their home. Furthermore, automation of all identified research questionnaires (above) will not be cost-effective for the research project as it is not included in the proposed research budget (which was approved by the VA Health Services Research & Development [VA HSR&D], Nursing Research Initiative [NRI] Scientific Merit Review Board).

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The research team will not ask respondents for any information that can be retrieved from the medical record (i.e. medical history, medications, etc.). However, the information collected via research questionnaires (i.e. Mini-Mental State Exam [VA Form 10-21085a NR], Functional Class: NYHA & SAS [VA Form 10-21085b NR], DISH [VA Form 10-21085c NR], BDI [VA Form 10-21085dNR], and MOS Social Support survey [VA Form 10-21085e NR]), are not part of routine practice in the care of patients with HF (both in the in-patient and outpatient hospital settings). Hence, information gathered via questionnaires is not available in the medical record. The attached instruments reference the above-named questionnaires. These questionnaires are public domain: Mini-Mental State Exam (VA Form 10-21085a NR), Functional Class: NYHA & SAS (VA Form 10-21085b NR), DISH (VA Form 10-21085c NR) and MOS Social Support survey (VA Form 10-21085e NR). A written permission was obtained from the Psychological Corporation to use the BDI (VA Form 10-21085dNR).

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB 83-1), describe any methods use to minimize burden.

The collection of information will not impact small businesses or other small entities.

6. Describe the consequence to Federal programs or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

a. If this one time study was not conducted, VA would fail in its mission to improve quality of life for Veterans and to use resources efficiently for the following reasons:

1) Heart failure, a common and costly condition at the VA health care system, has a high 6-month hospital readmission, morbidity and mortality. At the VA, HF is the most common diagnosis and is responsible for significant expenditures in the VA budget.[2] From 1997-1999, in 153 VA centers, an overall total of 21,994 Veterans were admitted with a diagnosis of HF. Veterans with HF had 30-day, 1-year and 2-year mortality rates of 5.5%, 22.3% and 34%, respectively.[3] For FY 2005, the total number of HF diagnoses at the VA GLAHS was 2464. From May 2004 to May 2005 and from May 2005 to May 2006, a total of 1,199 and 1,362 unique HF patients were seen at our local institution, respectively.

2) Recently, investigators have identified depression as comorbid to many chronic conditions including HF.[4] The impact of depression in influencing patients' noncompliance with therapeutic recommendations,[5] hospital readmissions,[6] death[7] and/or health care cost[8] has been reported. This study may provide insight on how depression and HF are related. It will identify the timing of depression in relation to hospitalization and will identify relationships of depression and/or biologic mediators to physical functioning in HF. By illuminating the relationship of clinical depression, physical functioning (via functional class measures) and biochemical markers in HF, this study may provide clinical insight in the development of an early, cost-efficient and cost-effective evaluation and treatment of depression among Veterans with HF.

NOTE: *see references at the end of submission*

7. Explain any special circumstances that would cause an information to be conducted more often than quarterly or require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; submit more than an original and 2 copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years; in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study and require the use of a statistical data classification that has not been reviewed and approved by OMB.

The special circumstance applicable to this research study is the conduct of collecting information more often than quarterly. To meet the objectives or purpose of the research study (identified in items # 1 and # 2), it is necessary to collect the information more frequently in the first quarter of the year of the respondents' (or subject participant) participation. The research objectives, research design and data collection procedures have been reviewed and approved by the VA Health Services Research and Development (HSR&D), Nursing Research Initiative, Scientific Merit Review Board (SMRB).

8a. If applicable, provide a copy and identify the date and page number of publication in the Federal register of the sponsor's notice, required by 5 CFR 1320.8 (d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in response to these comments. Specifically address comments received on cost and hour burden.

The notice of Proposed Information Collection Activity was published in the Federal Register on April 28, 2008 (Volume 73, Number 82, Page 23009). No comments have been received in response to this notice.

8b. Describe efforts to consult with persons outside VA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Explain any circumstances which preclude consultation every three years with representatives of those from whom information is to be obtained.

(1) Outside consultation is conducted with the public through the 60- and 30-day Federal Register notices.

Prior to submission of this research proposal (to VA HSRD Scientific Merit Review Board), consultation from Dr. Whooley was obtained in regards to the availability of data, frequency of collection, clarity of instruction, recordkeeping and/or reporting format. She has agreed with the study objectives, the corresponding type and frequency of data collection, and recordkeeping and reporting format. Currently, Dr. Whooley is a PI who evaluates depression among primary care patients. Additionally, she is an Associate Professor in Residence for the Departments of Medicine, Epidemiology and Biostatistics, University of California, San Francisco.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

The participants (or respondents) who consented to participate in the research study will be given a small amount of gift (that will amount to ≤ $ 20 e.g. grocery gift certificate, etc.). This amount is a token recognition for the respondent's time and effort to participate in the data collection that includes collection of blood specimen and administration of questionnaires. In research practice, this is a demonstration of respect and appreciation of the participants' (or respondents') generosity and sacrifice of time and effort in assisting investigators to generate knowledge (that is helpful to others and society.[9] The VA GLAHS Institutional Review Board (IRB) has reviewed and approved this modest gift (which was considered to be non-coercive) for respondents, who volunteer their time and efforts to participate in the research study. In addition, the budget for the respondent's gift was reviewed and approved by the VA HSR&D, Nursing Research initiative, SMRB.

To assure that this gift is not a cause of possible coercion or undue inducement, the investigators will initially obtained the informed consent of the participants (or respondents). Informed consent will involve providing the respondents the necessary information about the proposed study (which include a thorough understanding of the purpose, risks, benefits, alternatives and requirements of the study) that will allow them to decide voluntarily whether to participate or not participate in the study. After the participants or respondents has decided to participate in the research study, then they will be

informed about the modest gratuity that they will received as a token recognition of their time and effort.

NOTE: *see references at the end of submission*

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation or VA policy.

The information collected will be filed in research records. Information on these forms will become part of a system of records which complies with the Privacy Act of 1974. This system is identified as "Veteran, Patient, Employee and Volunteer Research and Development Project Records-VA (34VA11)" as set forth in the Compilation of Privacy Act Issuances via online GPO access at http://www.gpoaccess.gov/privacyact/index.html

11. Provide additional justification for any questions of a sensitive nature (Information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to him or her), such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Estimate of the hour burden of the collection of information:

a. Indicate the number of respondents, frequency of response, annual hour burden and explanation for each form is reported as follows:

Questionnaires	# of Respondents	Total # of Responses	min/ 60	Hourly Burden X 3 years
1. VA Form 10-21085a(NR) Mini-mental State Exam	218	1 X 218 = 218	X 5 mins (0.08 hr)	18.2 hours
2. VA Form 10-21085b(NR) Functional Class: NYHA/SAS scale	218	6 X 218 = 1,308	X 5 mins (0.08 hr)	109 hours
3. VA Form 10-21085c(NR) DSM-IV Diagnostic and Structured Hamilton	218	6 X 218 = 1,308	X 40 mins (0.67 hr)	872 hours
4. VA Form 10-21085d(NR) Beck Depression inventory	218	6 X 218 = 1,308	X 10 mins (0.17 hr)	218 hours
5. VA Form 10-21085e(NR) Medical Outcomes Social Support Survey	218	4 X 218 = 872	X 10 mins (0.17 hr)	145 hours

TOTAL		**5,014**		**1,362 hrs**

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB 83-1.

See chart in subparagraph 12a above.

c. Provide estimates of annual cost to respondents for the hour burdens for collection of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

In the Gantt chart (attached), data collection was spread from year 1 to year 3.

Form	**Rate**	**No. of Respondents**	**Total # of Responses x 3 years**	**Hourly Burden**	**Total Cost X 3 years**
VA Form 10-21085a(NR)	$15	218	1 X 218 = 218	(5 x 218)/60 = 18	$ 270.00
VA Form 10-21085b(NR)	$15	218	6 X 218 = 1,308	(5 x 1,308)/60 = 109	$1,635.00
VA Form 10-21085c(NR)	$15	218	6 X 218 = 1,308	(40 x 1,308)/60 = 872	$13,080.00
VA Form 10-21085d(NR)	$15	218	6 X 218 = 1,308	(10 x 1,308)/60 = 218	$3,270.00
VA Form 10-21085e(NR)	$15	218	4 X 218 = 872	(10 x 872)/60 = 145	$2,175.00
TOTAL			5,014	1,362	**$20,430.**

13. Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

a. There is no capital, start-up, operation or maintenance costs.

b. The only cost is for the time of the respondent.

c. There is no anticipated recordkeeping burden.

14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

For the entire period of the research study (4 years), the overall total costs to the Federal Government for each form (necessary to collect the information) are shown in the table below. The formulas used are as follows:

Questionnaires	Form Cost	Operational Expenses	X No. of responses	/ by 60	RN, II-3: $/hr	TOTAL COST
VA Form 10-21085a(NR) Mini-mental State Exam	0	$8.15	218	5 min. (.08 hr)	$33.80	$622.18
VA Form 10-21085b(NR) Functional Class: NYHA/SAS	0	$8.15	1,308	5 min. (.08 hr)	$33.80	$3,692.35
VA Form 10-21085c(NR) DSM-IV Diagnostic and Structured Hamilton	0	$30.00	1,308	40 min. (.67 hr)	$33.80	$29,503.60
VA Form 10-21085d(NR) Beck Depression Inventory	$5300	0	1,308	10 min. (.17 hr)	$33.80	$12,668.40
VA Form 10-21085e(NR) Medical Outcomes Social Support Survey	0	$8.15	872	10 min. .17	$33.80	$4,920.42
SUBTOTAL						**$51,406.95**

15. Explain the reasons for any burden hour changes since the last submission.

This is a new collection and all burden hours are considered a program increase.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

The results of the information collected for this research study will be published. For each of the research study objectives, a corresponding statistical analysis has been identified (see details in Section II: Collections of Information Employing Statistical Methods). The time schedule for the entire project is shown on the attached GANTT chart, which identifies the potential beginning dates and ending dates

of collection of information, completion of report, publication dates and other actions. These dates are dependent upon the approval of the Office of Management and Budget (OMB).

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

VA does not seek to omit the expiration date.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB 83-1.

There are no exceptions.

References

1. Goldman L, Hashimoto B, Cook EF, Loscalzo A. Comparative Reproducibility and Validity of Systems for Assessing Cardiovascular Functional Class: Advantages of a New Specific Activity Scale. *Circulation* 1981;64:1227-1234.
2. Ashton CM, Petersen NJ, Soucheck J, Menke TJ, Pietz K, Yu HJ, Wray NP. Rates of Health Services Utilization and survival in Patients with Heart Failure in the Department of Veterans Affairs Medical Care System. *American Journal of Medical Quality* 1999;14:55-63.
3. Deswal A, Petersen NJ, Souchek J, Ashton CM, Wray NP. Impact of Race on Health Care Utilization and Outcomes in Veterans With Congestive Heart Failure. *Journal of American College of Cardiology* 2004;43:778-784.
4. Evans DL, Charney DS, Lewis L, Golden RN, Gorman JM, Krishnan KRR, Nemeroff CB, Bremmer JD, Caarney RM, Coyne JC, Delong MR, Frasure-Smith N, Glassman AH, Gold PW, Grant I, Gwyther L, Ironson G, Johnson RL, Kanner AM, Katon WJ, Kaufmann PG, Keefe FJ, Ketter T, Laughren TP, Leserman J, Kyketsos CG, McDonald WM, McEwen BS, Miller Ah, Musselman D, O'connor C, Petitto JM, Pollock BG, Robinson RG, Roose SP, Rowland J, Shelline Y, Sheps DS, Simon G, Spiegel D, Stunkard A, Sunderland T, Tidbits P Jr, Valvo WJ. Mood Disorders in the Medically Ill: Scientific Review and Recommendations. *Biological Psychiatry* 2005;58:189.
5. Vaccarino V, Stanislav VK, Abramson J, Krumholz H. Depressive Symptoms and Risk of Functional Decline and Death in Patients With Heart Failure. *Journal of the American College of Cardiology* 2001;38:199-205.
6. Krumholz HM, Chen Y, Wang Y, Vaccarino V, Radford MJ, Horwitz RI. Predictors of Readmission AMong Elderly Survivors of Admission with Heart Failure. *American Heart Journal* 2000;139:72-77.
7. Murberg TA, Bru E, Svebak S, Tveteras R, Aarsland T. Depressed mood and subjective health symptoms as predictors of mortality in patients with congestive heart failure: a two-years follow-up study. *International Journal of Psychiatry in Medicine* 1999;29:311-326.
8. Sullivan M, Simon G, Spertus J, Russo J. Depression-Related Costs in Heart Failure Care. *Archives of Internal Medicine* 2002;162:1860-1866.
9. Grady C. Money for Research Participation: Does it Jeopardize Informed Consent. *ajob* 2001;1:40-44.

PREVALENCE & CLINICAL COURSE OF DEPRESSION AMONG PATIENTS WITH HEART FAILURE, VA HSR&D, NURSING RESEARCH INITIATIVE # 05-209-3
VA FORM 10-21085a,b,c,d,e(NR)
OMB 2900-XXXX

GANTT CHART

Project Title: Prevalence and Clinical Course of Depression Among Veterans with Heart Failure (HF)																				
RESEARCH ACTIVITIES	**Project Period Fiscal Year**																**Dissemination**			
	2008				***2009***				***2010***				***2011***				***(2012)***			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
IRB Approval Time																				
Hiring & Training of Staff																				
Patient Enrollment																				
Initial Data Collection																				
Follow-Up Data Collection																				
Data Management:																				
Data Entry																				
Data Imputations																				
Data Analysis																				
Presentations of Findings (Dissemination)																				
Final Report																				
Implementation Plan																				
Development Phase																				
Implementation Phase																				