Veterans, Researchers, and IRB Members Experiences with Recruitment Restrictions

OMB 2900-XXXX

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information.

This collection of information is necessary to complete a Veterans Health Administration (VHA) Health Services Research and Development (HSR&D) Service funded research study titled "Veterans, Researchers and IRB Members Experiences with Recruitment Restrictions". Research is an integral part of the VHA mission and important in advancing health care for Veterans. The VHA Office of Research and Development (ORD) has launched a Research Best Practices (RBP) initiative to study ways to improve the conduct of research within the VA. In support of this initiative, ORD's HSR&D Service solicited research projects that address the initiative's aims. We received funding through this process to conduct a study to examine whether current VA Institutional Review Board (IRB) policies pose barriers to recruitment of research study subjects and to explore Veterans' views on recruitment procedures.

All research studies involving human subjects must be reviewed by the IRB(s) affiliated with the institution(s) where the study will be conducted to assure participants are adequately protected. This includes review of recruitment methods. Studies show that IRBs vary in how they assess risks and hence apply restrictions. There has been little research on how IRB requirements impact study recruitment and whether they are necessary or effective in protecting potential research subjects. Some recruitment restrictions may hinder research progress or prevent qualified veterans from participating in research, while not increasing protection from harm. In assessing IRB rules on recruitment, it is important to consider the views of Veterans, whom the rules are intended to safeguard. Current policies have not been based on a formal assessment of Veterans' preferences. This study will use focus groups to gather information from Veterans about common issues related to research study recruitment including preferred methods of being contacted, privacy concerns, and the role of treating physicians in sharing study information.

Legal authority for this data collection is found under 38 USC, Part I, Chapter 5, Section 527 that 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 purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

Study investigators from four VA health care facilities will conduct focus group to gather information from Veterans about how they wish to be notified, contacted, and educated about research opportunities. All study data will be analyzed by the investigators using qualitative research methods to understand Veterans' preferences on research recruitment methods. The data will be published in peer-review medical literature and presented at the HSR&D national meeting, if accepted for such. Results may be used by researchers and VA Human Research Protection Programs (HRPPs) to develop more consistent and informed guidelines for recruitment practices. The results may be communicated to VA decision makers (Chief Research and Development Officer (CRADO), Directors of HSR&D, Clinical Services, Rehabilitation Services, and Director of the VA National Center for Ethics in Health Care).

This information has not been previously collected.

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, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Focus group discussions will be digitally audiotaped. This will allow free conversation and a means to preserve focus group content for systematic review. In-person focus groups, rather than an electronic survey, were chosen because the process of deliberative discussion that takes place in a focus group will allow subjects to debate and reflect upon aspects of research methods they may not have previously considered.

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.

We are not aware of the availability of similar information. VHA ORD's HSR&D Service solicited studies on this topic because of an identified need for this type information. A search of medical literature and VA HSR&D research studies cataloged on the VA HSR&D Service website was conducted at the time this project was developed; it did not reveal any similar data collections.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

No small businesses or other small entities are impacted by the information collection.

6. Describe the consequences to Federal program 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.

We will be unable to gather and report information which has been funded by the HSR&D Service with the goal of improving research conduct within the organization. As indicated, this study will collect information about how current IRB policies affect research recruitment and whether there are unnecessary barriers. Successful recruitment is necessary to complete studies in a timely manner and produce valid results. Veterans' preferences should be clarified before improvements are formulated.

The number of focus groups was chosen to include a range of VA sites and people with and without research participation experience. Fewer focus groups would not allow for an exhaustive discussion of topics.

7. Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three 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.

There are no such special circumstances.

8. a. 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 responses 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 October 31, 2013 (Volume 78, Page 211). We received no comments in response to this notice.

b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, 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.

Outside consultation is conducted with the public through the 60- and 30-day Federal Register notices. This collection will occur only once and will not continue beyond three years, so repeated consultation will not be relevant.

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

Focus group participants will receive $40.00 in the form of a voucher which can be redeemed for cash through the cashier at their VA Medical Center or by whatever payment method is allowed at their VA site. Payments of this type are acceptable practice in clinical research. This small incentive will increase likelihood of participation and help defer expenses associated with travel to the focus group site; yet, it is small enough not to be unduly influencing for approximately two hours of participation.

10. Describe any assurance of privacy to the extent permitted by law provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Focus groups will be conducted in a private room or area at each of the local sites. Focus group members will be instructed not to share information about fellow participants outside of the group. Any identifying information will be left out of interview transcripts. Site staff will have access to local focus group data. Transcripts will be coded with a subject number and stored separately from records with the interviewees' names and contact information; only study staff at the originating site will have access to the crosswalk linking subject identification number to identifying information for that individual. Paper records will be stored in locked file cabinets. Electronic files will be stored on restricted-access VA drives. Audio recording files will be stored securely or in the possession of VA study staff until downloaded; the audio files will be transferred to a restricted-access VA drive within 1-2 working days after the recording. All data will be kept indefinitely as required by current VA policy.

Principal investigators at alternate sites will have access to transcripts which do not contain any identifying information in order to assist with qualitative analysis. VA will share transcripts which do not contain any identifiable information with these investigators via e-mail.

Focus group participants are informed that study investigators will not share their information or identity unless required by law and that the research team will make every effort to protect your private

information, according to VA rules. Subjects will sign a Health Insurance Portability and Accountability Act (HIPAA) authorization for the use and disclosure of protected health information for research purposes because health information may be shared during the focus group. This authorization states: "The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Once your information is shared with another person or entity that you authorize by signing this form, the information may no longer be protected by Federal laws or regulations and may be given to someone else by the recipient."

Information collected 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. The number of respondents, frequency of responses, annual hour burden, and explanation for each collection is reported as follows:

Data collection	No. of respondents	x No. of responses	Equals	x No. of minutes	Equals		Number of Hours
Veteran focus group for study on recruitment restrictions	12 per focus group x 8 groups **96**	**1**	**96**	**120**	**11520**	**÷ by 60=**	**192**

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-I.

This request covers only one type of collection.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. 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.

VA does not require any additional recordkeeping. The cost to the respondents for completing the focus group is $4,608.00 ($24 per hour x 192 burden hours).

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

a. There are no capital, start-up, operation or maintenance costs.
b. Cost estimates are not expected to vary widely. The only cost is that 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, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

The annual cost is approximately $43,900. This includes costs for focus group participant payment and for personnel to organize, conduct, and transcribe the focus groups, as shown in the following table:

Primary Site Personnel (section A+B)	**Primary Site**	**Grade**	**Step**	**% Effort**	**Year 4** Salary+ Fringe
Project Coordinator	Portland	9	4	10	7340
Qualitative Analyst	Portland	12	2	5	5160
				Subtotal:	**12,500**

Additional Site Personnel	**Additional Site** (subaward)	**Grade**	**Step**	**% Effort**	
Site PI	TBD			2.5	3,800
Research Asst	TBD	7	1	5	5,600
				Subtotal:	**9,400**

Additional Site Personnel	**Additional Site** (subaward)	**Grade**	**Step**	**% Effort**	
Site PI	Bronx	13	8	2.5	3,800
Research Asst	Bronx	7	1	5	5,600
				Subtotal:	**9,400**

Additional Site Personnel	**Additional Site** (subaward)	**Grade**	**Step**	**% Effort**	
Site PI	TBD			2.5	3,800
Research Asst	TBD	7	1	5	5,600
				Subtotal:	**9,400**

Other	**Site**				
Participant Incentives	Portland				800
Participant Incentives	TBD				800
Participant Incentives	Bronx				800
Participant Incentives	TBD				800

Subtotal: 3,200

TOTAL: 43,900

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15. Explain the reason for any burden hour changes or adjustments reported in items 13 or 14 of the OMB form 83-1.

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.

Data will be analyzed using qualitative content analysis. Patterns that emerge from the data will be summarized and described including Veterans' preferences about being notified about research, their concerns about different types of recruitment methods, what role their physician should play in the process, what information should be included in recruitment letters, what concerns they have about confidentiality, what role trust of researchers plays, and how risks and burdens influence their choices. Other themes may emerge and these will also be reported.

The results will be published in peer-review medical literature if accepted for such. We estimate focus groups will be conducted and transcribed from June 2014 through March 2015. A manuscript summarizing results will be completed and submitted to a medical journal for review by approximately September 2015. If the manuscript is accepted for publication, the publication date is determined by the publishing journal.

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

The OMB expiration date will be stated to all focus group participants.

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

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

No statistical methods are used in this data collection because the method is qualitative.