Date: 07/02/2009

From: PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject: Request for Approval of FDA Focus Group, Identification of Barriers and Opportunities for Clinical Research; OMB Control No. 0910-0497

To: Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer _____

The Food and Drug Administration (FDA), Division of Epidemiology (DEPI) in the Center for Devices and Radiological Health (CDRH), Office of Surveillance and Biometrics (OSB) is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group, "Identification of Barriers and Opportunities for Clinical Research", to get the opinions of Clinical Research Coordinator (CRC) who are responsible for the day to day activities of clinic trials, and thus the success of the trial. Nine (9) focus group participants will be asked to identify barriers and opportunities for obtaining complete, accurate, and representative data for post-approval studies of medical devices.

A. Justification:

1. Circumstance or need that make the collection necessary

Increasingly, the FDA has placed an emphasis on postmarket medical device safety. There also has been an increased focus on the importance of postmarket research and value of collecting long-term data and the postmarket experience with use of medical devices in a "real world" setting. Limited resources make it crucial to design and conduct research in an efficient manner. This includes ensuring that study populations are representative of the intended use population, adverse events are reported accurately and in timely manner, participant retention is maximized, and losses to follow-up are minimized.

There is a great need to identify barriers to and opportunities for obtaining complete, accurate, and representative data. Valuable information on these barriers and

opportunities can be obtained from those with “hands on” research experience. Although the Principal Investigator (PI) is legally responsible for the conduct of the research, the Clinical Research Coordinator (CRC) is the heart and soul of the research study. It is the CRC who is responsible for the day to day activities, and thus the success of the research study. The CRCs are often directly responsible for essential tasks in conducting research and ensuring compliance with the protocol. The CRC’s responsibilities include identifying and screening potential participants, participant recruitment, administering informed consent, adverse event reporting, completion of the case report form (CRF), and obtaining participant follow-up.

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

This information will be used by DEPI to improve implementation strategies for post-approval studies. During the past several years CDRH has made a significant commitment to enhance the Post-Approval Studies (PAS) Program. CDRH considers PAS to be an important public health tool. In order for PAS to be most effective, they must be well-designed, scientifically sound, meaningful and feasible, and they must provide complete and timely information. It is important to receive input from stakeholders directly involved in collecting and analyzing data relevant to estimating medical device use and risk.

3. Described efforts to identify duplication

A literature search was conducted using Pubmed, Embase, and Web of Science databases. There were no publications identified that discussed the implementation strategies for obtaining complete, accurate, and representative data for post-approval studies of medical devices. The literature search did reveal some publications on recruitment and retention in pharmacologic trials. However, implementation issues pertinent to drug trials may not be applicable to device trials. In addition, implementation of post-market trials have their own unique set of issues and solutions for which there has been little documentation.

4. Describe the consequence to Federal program or policy activities if the collection is not conducted.

If this focus group is not conducted, the FDA will not be able to provide scientifically based advice to manufacturers required to conduct Post-Approval Studies. Expert opinion on how to increase enrollment and maintain high follow-up rates in postmarket studies of medical device is urgently needed.

5. Describe efforts to consult persons outside the agency

DEPI will collaborate with the Association of Clinical Research Professionals (ACRP) on identifying volunteer participants for the focus group. ACRP provides members with training and offers the designation of Certified Clinical Research Coordinator. Members of ACRP represent an excellent resource on the barriers of conducting post-marketing surveillance studies. Members are from all 50 states and outside the US. They represent all trials conducted in all research areas for device, drugs, biologics, and combination products. ACRP has an electronic membership list that can be used to identify potential qualified participants.

6. Explain any decision to provide any payment or gift to respondents.

Focus group participant will be paid a stipend of $75.00 each to compensate them for their time. The target participants are professionals who are employed either part or full time as a Research Coordinator. It was felt that to encourage participation, a monetary stipend was needed. The $75.00 amount is comparable to a rate a Research Coordinator would be paid for 1.5 hours of work.

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

ACRP will provide initial electronic communication with a list of ACRP CRC members in the metro-DC area. Participants will be ACRP members who have worked as clinical research coordinators on postmarket device studies. Names of participants will be known to ACRP and a qualified external focus group facilitator, but no individual participant information will be made available to FDA. Information obtained will be recorded in such a manner that subjects can not be identified, directly or through identifiers.

8. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that commonly considered private.

No questions of a sensitive nature will be addressed during this focus group

9. Provide estimates of the hour burden of the collection of information. (note- for focus groups this should include both the screening process and the actual focus group time)

Respondents	Annual Frequency	Total Annual Responses	Hrs Per Response	Total Burden Hours
Screening Estimate will get 25 inquiries	This is a one time focus group. This will not be on an annual basis	25 inquiries	10 minutes per Inquiry	4.2 hours (calculated as 250 minutes)
Actual focus group 9 respondents	This is a one time focus group. This will not be on an annual basis	9 responses	1.5 hours per respondents	13.5 hours (calculated as 9 respondents for 1.5 hours)
TOTAL				17.7 hours

10. For collections of information whose results will be published, outline plans for tabulation and publication. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information completion of report, publication date and other actions.

The planning phase of the focus group will take place in August 2009. This will include the development of the moderator's guide, finalizing questions, and planning the logistics of focus group. The focus group will be conducted between September and December 2009. The report will be completed by a contractor with expertise in facilitating and documenting focus groups. The final report will be submitted within 30 days of the focus group session. Abstracts, presentations or publications resulting from analysis of these data will contain only summary data, so individuals cannot be identified.

If you have any questions, please contact Denver Presley on 301- 796-3793