FDA Generic IC under 0910-0497 : Identification of barriers and opportunities for clinical research

TERMS OF CLEARANCE

Consistent with the supporting statement for the umbrella generic ICR 0910-0497, FDA recognizes that focus groups are appropriate for formative research (e.g. to test and refine ideas) but are not appropriate for driving the development of policies, programs, and services.

OMB is supportive of FDA's efforts to improve recruitment and retention in phase 4 clinical trials of medical devices, particularly if there is no literature or research on this particular topic. However, we do not believe that it is appropriate to use anecdotal data from one focus group of 9 participants to issue any guidance – even informal guidance for use within the agency – on recruitment and retention techniques. Further study is required to have more confidence in the data obtained.

FDA agrees that this focus group is just the first step in gathering the type of data needed to provide guidance on common practices or best practices with regard to recruitment and retention for phase 4 trials of medical devices. FDA further agrees that it will not issue any guidance –even informal guidance for use within the agency – on the basis of this one study. Before FDA issues any such guidance, FDA agrees to conduct further study (e.g. a survey to further explore issues or areas of interest that emerged from this focus group, further focus groups, etc.).

Finally, FDA is approved to provide an incentive of $75 per focus group participant.

OMB Passback and FDA Responses

1. Please clarify how FDA intends to use the information from this study. Does FDA intend to use these data to "provide scientifically based advice to manufacturers required to conduct Post-Approval Studies" (response to question 4)?

FDA would like idenfify the barriers to recruitment and retention in post approval studies. The recruitment of a representative population of those who have the disease or are treated for a condition is important in evaluating the safety and effectiveness of medical devices. In addition, it is important that the studies mantain a high rate of follow-up (>80% is recommended). Many times sponsor's indicate they have a problem with recruitment and retention of participant. The information gathered will help FDA identify barriers and best practices for recruiting and maintaining follow-up. This will enable FDA to provide sponsor's advise on how to recruit and retain patients, thus ensuring the best possible data is gathered in the post market trials.

2. Will FDA pick focus group participants on the basis of any particular criteria? If so, what are those criteria?

Focus groups participants will be indentified form a list of ACRP members. Those who live in the DC metro area, indicated that they have participated in phase 4 trials, and device trials will be identified in the ACRP database. These participants will be recruited first. This will be followed by those living in the DC metro area who have participated in phase 4 drug trials.

3. Please explain the choice of a $75 incentive. The justification appears to be based on the wages of a Research Coordinator rather than on experience with the ability to recruit Research Coordinators for studies such as this. How difficult would it be to recruit 9 Research Coordinators for, say, $25? $50?

It has been recommend that the incentive be changed to $100. This is based on a recommendation by ACRP and Shuggal Reseach. This is the incentive payment that has been made for similar studies. Rates $25 or $50 would not be able to recruit the needed population.