Terms of Clearance: Risk Managers' Focus Group: Adverse Event Reporting Practices for Tissue and Cell Products

OMB Control No	Current Expiration Date	ICR Ref. No	Agency/Sub	Title	Request Type
0910-0497	02/28/2011	200803-0910-002	HHS/FDA	Risk Managers' Focus Group: Adverse Event Reporting Practices for Tissue and Cell Products	Gen IC

Per the supporting statement for the Umbrella Generic ICR, "Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus group findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies."

As such, this generic IC, under the Umbrella Generic ICR 0910-0497 ("Focus Groups as Used by the FDA"), is approved on the understanding that this focus group is but the first step in a multi-step research project and that FDA plans to undertake further research before using these study findings to make any policy or resource allocation decisions, including the issuance of any guidance documents. FDA also agrees to submit a summary report of the study results of the focus group. That report will identify FDA's intended next steps for further research.

FDA Memo of 11/25/09:

Yes OBE/DE attests that further research will be conducted before these results are used. Upon completion of the focus group session, we will prepare and submit a report summarizing the focus group. The report will also identify our intended next steps for understanding tissue and cell adverse event reporting practices and interpretation of current guidelines and regulations. Thanks very much for your continued help with this,