

ATTACHMENT 22
Statement of Exemption from 45 CFR 46

DATE: August 20, 2006

TO: Reports Clearance Officer, DHHS

FROM: Director, Office of Education and Special Initiatives, NCI

SUBJ: Pretesting of NCI's Office of Communications Messages (OMB No. 0925-0046)

I have reviewed the supporting statement to OMB requesting a three-year extension for pretesting its messages and materials and have determined it to be exempt from the **Regulations for Protection of Human Subjects**, as defined in Paragraph (b)(3) of 45 CFR Sec. 46.101.

The pretesting and formative research described in this statement consists entirely of surveys and interviews. Data collection instruments are designed to ensure that the messages and materials we produce and disseminate are relevant, meaningful, and sensitive to our various target audiences, including members of the public, cancer patients and their families, and underserved and minority audiences. NCI must demonstrate a high degree of care and sensitivity in all its communication efforts and data collections. While the subject of cancer is somewhat sensitive, our experience from many previous focus groups is that people talk quite freely about health matters today and welcome the opportunity to share their experiences and/or fears about cancer with people like themselves.

Additional safeguards have been put in place to protect respondents from risk. For example, after the data from surveys and interviews have been collected, identifiers (if any) are not retained, and there is no way to trace particular responses to individual respondents. In addition, recruiting and recording instruments (e.g., screeners, interview tapes) are destroyed once the data have been aggregated.

In summary, the standard pretests conducted by NCI generally place us into the exempt category with regard to 45 CFR 46. In addition, as of August 2006, all work conducted under this clearance package is being submitted to the Office of Human Subjects Research (OHSR) in order to receive an official exemption status from IRB requirements. However, if a project should arise having an increased degree of sensitivity (e.g., interviews on genetic testing), we would certainly consult further, seeking approval from an authorized IRB.



Lenora Johnson
Director
Office of Education and Special
Initiatives (OESI)
National Cancer Institute (NCI)