

DEPARTMENT OF HEALTH & HUMAN SERVICES

**National Institutes of Health
Bethesda, Maryland 20892**

March 22, 2009

TO: Office of Management and Budget (OMB)
Through: Reports Clearance Officer, DHHS
Project Clearance Chief, NIH

FROM: Laura Lee, RN, BSN
Clinical Center

SUBJECT: Satisfaction Surveys of Customers and Other Partners
0925-0458 - EXP. DATE: 11/30/2010

This is a request for OMB to approve a **Survey of Acute Graft Versus Host Disease (GVHD) Practice Patterns**. The staff of the Clinical Center plan to conduct this survey under OMB Control Number 0925-0458, expiration date November 30, 2010. The goal of this survey is to query investigators/practitioners regarding the type of therapy provided to patient with GVHD in their institutions and to collect information about the end-points investigator/practitioners use in treating this patient population. This information will be used to inform practice and policy decisions about the care of patients with GVHD.

Circumstances Making the Collection of Information Necessary

At the present time, there is no published consensus on the treatment on acute GVHD, nor on the scientifically acceptable endpoints for clinical trials of treatments for acute GVHD. HRSA and NIH fund a registry of outcomes for patients undergoing stem cell transplantation, and acute GVHD incidence, treatment and outcome are elements of the registry, but the practices underlying the data collected about GVHD are not known.

Purpose and Use of the Information Collection

This survey will assess the practice patterns of investigators/practitioners in the United States and internationally caring for, and conducting clinical research with, patients with GVHD.

An email invitation to participate will be sent to approximately 400 respondents. The survey is a web-based self-administered questionnaire. Completion will be voluntary with no payment and individual responses will be kept confidential. Findings will be used by CC and NCI staff as a pre-text for discussions to be held at the NIH-FDA sponsored public workshop on clinical trial endpoints in acute GVHD.

Estimate of Burden Hours and Costs

Estimates of Annual Hours Burden Self-administered web-based survey				
Types of Respondents	Number of Respondents	Frequency of Response	Average Hours Per Response	Annual Hour Burden
Researchers, Physicians,	400	1	.167	67 hrs (\$0.00 cost)