



**Southwest
Oncology Group**

A National Clinical Research Group

February 15, 2009

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP AND
AFFILIATE MEDICAL ONCOLOGISTS

FROM: SOUTHWEST ONCOLOGY GROUP OPERATIONS OFFICE

RE: SWOG-8921, SWOG-8935, SWOG-9112, SWOG-9328, SWOG-9338, and
SWOG-9438

MEMORANDUM

The Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), NCI has withdrawn the DCTD-sponsored IND for Recombinant Human Interleukin-2, NSC-373364, **effective May 2, 2008**. Their records indicate that all DCTD-sponsored studies using this agent are closed and that all patients are off treatment with this agent.

FDA regulations require investigators to retain all research records, including patient charts, case report forms, x-rays and scans that document response, IRB approvals, signed informed consent documents and all drug accountability records for at least two years after the IND has been withdrawn. Please retain records until at least **May 2, 2010** (45 CFR 46.115 specifies that IRB records must be kept for 3 years-until May 2, 2011).

The Pharmaceutical Management Branch, CTEP has previously sent letters to all CTEP investigators and their designees to whom this agent was supplied, advising them that CTEP was withdrawing the IND for this agent and requested the return of all CTEP-supplied Recombinant Human Interleukin-2, NSC-373364. If you have not already done so, please return all CTEP-supplied Recombinant Human Interleukin-2, NSC-373364 to the NCI Clinical Repository at 627 Lofstrand Lane, Rockville, MD 20850 ATTN: RETURNS. FDA regulations require all remaining supplies of this agent to be returned to the IND sponsor.

Please feel free to contact Dr. Jan Casadei for any regulatory questions and Mr. Charles Hall for any agent supply issues.

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