

March 1, 2008

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP, UCOP AND AFFILIATE

MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS,

PATHOLOGISTS AND CLINICAL RESEARCH ASSOCIATES

FROM: SWOG Operations Office

RE: NEW MRU CODES

MEMORANDUM

Beginning with the March 1, 2008 mailing, you will see a new feature in the Clinical Trials pages of swog.org. In an effort to make things easier and more foolproof for us all, we are adding codes that indicate the minimum actions required by SWOG for protocol amendments and revisions. These are the codes that will be used:

IP - Pts Must Be Informed

AC - Consent Must Be Amended

CBR - No Registration Allowed Until IRB Review

RC - Formal Re-consent Required

FBR - Full Board Review Required

ER - Expedited Review Acceptable

NR - No IRB Review Required

We hope that these codes are basically self-explanatory and will be easy to recognize and use. The meanings of the codes, however, can always be found either at the bottom of the page or, where the words <u>Action Code(s)</u> are underlined on a web page, in a pop-up window. The codes will be found wherever Most Recent Updates are found in the Clinical Trials section of swog.org: the Protocol Abstract page, the Previous Updates window, and the What's New page.

These codes will be introduced gradually over the next few months, starting with the protocols that have 3/1/08 amendments and revisions, then will appear with all open protocols, then with some high-accruing closed protocols.

It must be emphasized that these codes are intended as aids, not as the definitive indicator of required action on a protocol amendment or revision. Particularly during the start-up period when the codes are gradually appearing on our clinical trials web pages, the cover page of all amendments or revisions should be checked to ensure that the required actions are taken. If you do not see a code associated with a particular protocol change on the web site, please check the cover page associated with that change on the protocol itself.

