

**MEMORANDUM**

**TO:** SWOG Protocol Users  
**FROM:** SWOG Operations Office  
**DATE:** August 1, 2007  
**SUBJECT:** "Authorization" of SWOG Protocol Documents

Effective with the August 1st protocol distribution, the Southwest Oncology Group will begin issuing its protocol documents in an "authorized" format. We will begin with the protocols that are changed effective with the August 1st protocol distribution, but hope to have all protocol documents placed into authorized format over the next several months.

Authorization of our pdf files means that SWOG attests to a document's contents at the time it was issued, and any changes made to the document after that point will invalidate the authorization. The authorization (see immediately below) will appear with the SWOG logo in the lower right corner of all pages of SWOG protocol documents (excluding the pdf versions of the online data submission forms).



The practical effect of this is that **text may now be copied from these documents** as necessary to meet local needs such as IRB applications, grant reports and internal status reports. The authorization process is handled totally at the Operations Office and requires no effort from the protocol users at the sites. Aside from access to text from SWOG protocols, the protocol users should notice no difference in their access to or use of the protocols.

Our intent has always been to protect the integrity of the approved protocol documents and to ensure that there are no local changes made to the existing protocols (in order to protect both patient safety and the performance of the study). Our old system of locking the protocol documents was quite restrictive in that the text in the documents could not be copied and used for other purposes (for fear of allowing the possibility of creating a duplicate document that could not be distinguished from the original).

We are now able to authorize a version of the document that is the official protocol for SWOG purposes and for the performance of the SWOG research study. This will allow portions of the document to be copied for other purposes, however the danger of creating a duplicate document no longer exists – as the duplicated document will not contain the original document's authorization from SWOG. The Group will be developing policies to address the use of authorized documents and this information will be available to you soon.

As the use of electronic source documents becomes more and more prevalent, the systems for ensuring adequate documentation of electronic records for audit purposes also becomes more crucial. We anticipate that confirmation that the institution is using the authorized SWOG protocol documents will become a standard part of the SWOG audit process.

We hope that you will appreciate the flexibility of being able to copy text from SWOG protocols. We see this as a big step forward into a more efficient system of protocol information sharing – and we hope that you agree. If you have any questions about this process, please contact the Operations Office at 210-450-8808 or [web@swog.org](mailto:web@swog.org).  
PC/dbs

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**Operations Office**