

April 15, 2018

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[swog.org](http://swog.org)

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS  
FROM: SWOG Operations Office  
RE: NIH Policy for Issuing Certificates of Confidentiality for SWOG Studies

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**MEMORANDUM**

The purpose of this memorandum is to inform sites of the SWOG studies subject to the NIH Policy for Issuing Certificates of Confidentiality and of the sites' responsibilities for informing patients of the protections provided by the Policy.

On September 7, 2017, NIH released their Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality ("Policy," effective 10/1/17). The full Policy is available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>. As part of the Policy, all research commenced or ongoing on or after 12/13/16 and within the scope of the policy is deemed to be issued a Certificate of Confidentiality through the Policy, and therefore is subject to the Policy. Anyone conducting research issued a Certificate of Confidentiality under this Policy is required to protect the privacy of individuals who are subjects of the research in accordance with subsection 301(d) of the Public Health Service Act. Note that the full scope is outlined in the Policy; however, for SWOG's purposes, the Policy covers all studies which are at least partially funded by SWOG's federal research grants. Sites are encouraged to review the Policy to review the requirements for establishing and maintaining internal controls to comply with the Policy.

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

This memorandum serves to notify the NCI and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE