

April 15, 2020

TO: ALL NATIONAL CANCER CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NATIONAL COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) COMPONENTS AND SUBCOMPONENTS

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: Protocol-Specific COVID-19-Related Allowable Deviations

MEMORANDUM

The purpose of this memorandum is to inform sites that SWOG is preparing and distributing documentation for protocol-specific allowable deviations to address anticipated study-specific issues related to the extenuating circumstances occurring as a result of the COVID-19 pandemic.

Note that SWOG provides real-time COVID-19 information and updates via the [SWOG COVID-19 clearinghouse](#). Please see the clearinghouse for the most recent information available from NCI, CIRB, FDA, and SWOG, including a [continuously updated list of biobanks and laboratories](#) taking SWOG study samples.

Participating sites are encouraged to refer to the NCI memoranda for general guidance on continuity of care, administration of investigational agents, use of telemedicine, remote consent, and documentation of deviations, respective to COVID-19 extenuating circumstances.

In addition to the allowable deviations noted in the regulatory memoranda, SWOG will prepare and distribute allowances on a protocol-specific basis to address protocol requirements that the Study Chairs and SWOG leadership anticipate may be problematic in the current COVID-19 pandemic circumstances. The protocol-specific memoranda will be available with the other protocol-related documents on the SWOG and CTSU websites (www.swog.org and www.ctsu.org). The list of studies for which protocol-specific COVID-19-related allowable deviation memoranda have been distributed or are being developed is as follows:

- S0820
- S1001
- S1404
- S1418
- S1501
- S1512
- S1607
- S1608
- S1613
- S1616
- S1703
- S1714
- S1801
- S1803
- S1806
- S1815
- S1826
- LungMAP
- S1916

The operational allowances outlined in these memoranda still constitute minor protocol deviations. Sites must thoroughly document and report the COVID-19 circumstances and details of the deviation. SWOG is currently developing and centralized reporting mechanism/process and will distribute instructions for reporting of minor deviations to SWOG (as indicated in the NCI memorandum) when finalized. These deviations will not result in deficiencies at the time of audit.

Please utilize the contact information noted on individual protocol-specific memoranda for questions regarding each study.

cc: CTEP PROTOCOL & INFORMATION OFFICE
DCP PROTOCOL & INFORMATION OFFICE