

June 15, 2020

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCORP COMPONENTS AND SUBCOMPONENTS

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

RE: Interim COVID-19 Guidance – SWOG Study-Specific Memorandum

MEMORANDUM – Interim COVID-19 Guidance

The purpose of this memorandum is to inform sites that the allowable timeframe for implementation of SWOG protocol-specific variances specified in SWOG Interim Guidance Study Specific Memoranda distributed for the following SWOG studies has been extended. Until further notice, there is no expiration date for the COVID-19 allowable COVID-19 variances specified in the SWOG study-specific memoranda for the following studies.

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|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| Lung-MAP | <u>S1007</u> | <u>S1418</u> | <u>S1607</u> | <u>S1616</u> | <u>S1714</u> | <u>S1806</u> | <u>S1826</u> |
| <u>S0820</u> | <u>S1207</u> | <u>S1501</u> | <u>S1608</u> | <u>S1702</u> | <u>S1801</u> | <u>S1815</u> | |
| <u>S1001</u> | <u>S1416</u> | <u>S1512</u> | <u>S1613</u> | <u>S1703</u> | <u>S1803</u> | <u>S1820</u> | |

Participating sites are reminded that the variances specified in the memoranda for the above-referenced studies must be resultant from COVID-19 pandemic extenuating circumstances and must be documented as minor protocol deviations in accordance with local institutional procedure.

Similarly, in the [June 2, 2020 Updated NCI guidance memorandum for shipment of Oral IND Agents](#), the NCI has extended the allowable timeframe for the allowance of Shipment of Oral IND Agents to Clinical Trial Subjects, previously specified in the [March 23, 2020 NCI guidance memorandum for shipment of Oral IND Agents](#), from June 14, 2020 to September 13, 2020. SWOG will follow NCI's guidance for timeframe for allowing shipment of oral agents with IND's held by SWOG.

As a reminder, SWOG provides real-time COVID-19 information and updates via the SWOG [COVID-19 clearinghouse](#). In particular, resources currently posted on the clearinghouse that participating sites may find helpful for conduct of SWOG clinical trials during the COVID-19 pandemic include:

- [SWOG Cancer Research Network Laboratory Status Memorandum](#) – Specifies laboratory status and procedures for all SWOG protocols utilizing laboratories for direct specimen shipment other than the SWOG Biospecimen Repository
- [SWOG Active Protocol Specimen Guidance Memorandum](#) – Specifies level of priority and allowances for later shipment (if resultant from COVID-19) for all specimen types and timepoints for each active SWOG protocol.
- [SWOG Interim COVID-19 Guidance Memorandum for Eligibility Visits and H&P Assessments](#)
- [SWOG COVID-19 Deviation Guidance Memorandum](#) and associated [SWOG COVID-19 Deviation Log](#) (paper form)
 - A mechanism for reporting COVID-19 minor protocol deviations in RAVE is still forthcoming.
 - Meanwhile, sites are responsible for documenting minor deviations per local institutional procedure.
 - Use of site-specific protocol deviation logs is acceptable provided that the log captures the same information contained on the SWOG COVID-19 Deviation Log. This information will subsequently be requested for submission via RAVE when the reporting mechanism is rolled out.
- [NCI CIRB COVID-19 FAQ](#)
- [March 23, 2020 NCI guidance memorandum](#)
- [March 13, 2020 NCI guidance memorandum](#)

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

cc: PROTOCOL & INFORMATION OFFICE