

# Protocol Briefing

## *ALLIANCE CCTG CE.7 – A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases*

| <b>Requirements</b>                        | <b>Yes/No</b> | <b>Details</b>  |
|--|---------------|---|
| <u>Study Drug Supplied</u>                 | No            | Memantine – ALL commercially supplied.  |
| <u>Lab Requirements</u>                    | Yes           | <ul style="list-style-type: none"> <li>MANDATORY Biospecimens – See Section 5.0 &amp; Correlative Studies Manual posted on CTSU website for information collection and required time points. Specimen collection kits are not being provided for specimen submissions; sites will use institutional supplies. Optional samples for banking.</li> </ul>  |
| <u>Questionnaires</u>                      | Yes           | <ul style="list-style-type: none"> <li>QOLs completed on paper and entered into RAVE, see CTSU protocol page for paper QOLs. See Section 5.0 for required time points.</li> <li>Neurocognitive Assessments are required per Section 5.0 and Appendix VII. Order required Neurocognitive Assessment booklets prior to registration. Please see CTSU Supply Request Form on CTSU study page for ordering booklets.</li> </ul> |
| <u>Tissue Submission</u>                   | No            |   |
| <u>RT Credentialing</u>                    | Yes           | Stereotactic radiosurgery (SRS) credentialing, see Section 7.5.   |
| <u>Radiology Requirements</u>              | Yes           | MRI of the Brain – See Section 5.0 for required time points.  |
| <u>Disease Assessment Requirements</u>     | Yes           | RANO-BM Criteria – See Section 8.2 & 8.3.   |
| <u>Training Requirements</u>               | Yes           | Neurocognitive Assessment training – see Appendix VII. Cross credentialing allowed for sites already credentialed for BN001, CC001, CC003, & N0577. Please submit credentialing certificates to Amber Boerner, <a href="mailto:aboerner@mtcancer.org">aboerner@mtcancer.org</a> , for submission to CTSU.   |
| <u>CIRB, Local IRB, or Commercial CIRB</u> | CIRB          |   |
| <u>Miscellaneous</u>                       | No            |   |