OHRS Guidance on Potential Protocol Deviations and Violations Related to Global Omnipaque Shortage:

Due to a temporary global shortage of contrast agent, the IRB understands the need for flexibility related to research imaging during this time. The following guidance is intended to clarify how to submit prospective changes to protocol imaging plans and report protocol deviations for IRB review.

Disruptions to scans as a result from the global Omnipaque shortage will *not* be treated as major protocol violations or protocol non-compliance. During this time, the PI is ultimately responsible for deciding whether immediate action is needed to protect the safety and well-being of study participants.

Make a prospective plan for imaging (preferred option)

OHRS encourages each PI to evaluate their protocols prospectively and determine which scans must be obtained as planned and which may be eliminated or modified. The standard of care scans should be prioritized over purely research scans.

- The revised imaging plan (along with any relevant sponsor correspondence) may be submitted as a prospective deviation request. This request will be protocol-specific rather than patient-specific.
- These prospective deviation requests will be approved for a limited period on the IRB Outcome Letter (i.e., 3 months).
- Prospective deviations approved in this process will not need to be tracked and reported at continuing review.

Follow temporary process for reporting disrupted scans (alternative option)

Imaging scans (not otherwise noted in the revised imaging plan above) may be disrupted or altered as a result of this shortage.

- For each study affected by disrupted or unexpectedly altered scans, please list deviations and violations using the minor violation/deviation log submitted with the annual continuing review.

*This plan is in effect for the next 3 months; This plan may be renewed by OHRS if needed.