S

Risk Level Assignment

5.1 Prior to study start up, all new Investigator Initiated Trials (IITs) will be reviewed and assigned a risk level by the Cancer Center Scientific Review Committee and confirmed by the Cancer Center Data Safety Monitoring Committee (DSMC). QA oversight will be based on the risk level of the study. The QA team will use Cancer Center Data Safety Monitoring Plan as a framework for reviews. Any aspect of the review may change at the discretion of the QA team due to factors such as time and resource constraints. Changes will be documented accordingly.

Selection of Trials

5.3. Trials will be selected for directed IQARs or routine IQARs. Directed IQARs (i.e., "for cause") may be initiated per the request of the DSMC, IRB, Research Manager, Physician Investigator, or Administrative personnel. Directed IQARs may include a review of trials being coordinated by new CCCTO employees. Routine IQARs will focus primarily on IITs. Subject(mar)-0.99.u3.8 (j)]02 Tc 4Qu1d(l)0.9 (y)-6.38

Follow- up

5.10 A written final report will be provided to the study team and Faculty Committee Coordinator after completion of the IQAR. All findings, recommendations, and action items will be detailed in the final report.

5.11 A written response to the final report should be provided to the QA staff within 30 days of receipt of the final report. The study staff may request an extension for considerable conflicts.

5.12 A copy of the report and the responses will be filed with the CCCTO QA staff and uploaded to Oncore. A copy of the report will be provided to the Cancer Center Data Safety Monitoring Committee.

5.13 A follow up IQAR or further external auditing may be recommended based on the IQAR findings (e.g., Clinical Translational Science Institute-CTSI, MCW Office of Research, etc.).

6.0 REFERENCES

Oversight of Clinical Investigation – A Risk-Based Approach to Monitoring, US Department of Health and Human Services, Food and Drug Administration, August 2013

7.0 APPENDICES

Appendix I: Definitions

Authorized by: _____ _____

James Thomas, Medical Director