Memorandum

To: Dr. Lou Gonsalves

From: Dr. Anne Betzner, Dr. Ann Wendling

Date: 10/24/11

Re: **Progress Evaluation of the Connecticut Biorepository Project**

This memorandum briefly assesses the progress of the Statewide Tumor Tissue Biorepository Feasibility Study and Lung Tissue Biorepository Demonstration Project against the original contract deliverables that have been modified. The Connecticut Department of Public Health (DPH) contracted with the University Connecticut Health Center (UCHC) to complete grant activities starting on January 26, 2010. The DPH has provided UCHC two no cost extensions, essentially doubling the project duration. Contract activities are now scheduled to be completed on December 31, 2011 with a Final Report due within 60 days of completion. This memo uses [illegible]al Report and Table of Deliverables submitted to DPH on October 10, 2011 for [illegible]fied contract deliverables are italicized.

[illegible]*ity Study Report* was to be reviewed twice by the Advisory Panel with [illegible]t by External Reviewers prior to final submission to DPH. This was [illegible] by Week 26 (July 27, 2010). The draft feasibility report is now considered to [illegible]n the Draft Final Report. Comment will be received when the Draft Final [illegible]ed to Advisory Panel members after its second meeting in November. The Final [illegible]dy Report will be submitted in December, 2011. This will include establishment of [illegible] and procedures and outstanding issues for the now primary Demonstration Project, the Statewide Virtual Biorepository (VB) (referred to now as Accelerated Tissue Access, or ATA).

*Therefore, we see the deliverables from the original contract will largely be completed under the revised contract; however, there will be limited review of the Study Report before its final submission.

Demonstration Projects:
Limited progress had been made in implementation of the ***Prospective Collection and Storage of Fresh-Frozen Tissue (FFT) and Serum (Blood) Project*** with implementation originally scheduled for Week 26 (July 27, 2010). The FFT project had been implemented on a small scale at UCHC and Yale, but other hospitals had not been finalized. *An interim report on this project was scheduled (per contract) to be submitted to DPH by Week 44 at the latest (November, 30, 2010).* The report is now considered to be part of the Draft Final Report. The project is now referred to as the ***Cryopreserved Specimen Repository (CSR).*** Brief descriptions of the challenges involved with this project are contained in Sections 100, 400 and 800. Appendices 7000 and 9000 contain the IRB and Operating Procedures, respectively.

The implementation of the ***Physical Biorepository of Formalin-Fixed Paraffin-Embedded (FFPE) Tissue Project*** at Hartford and a third hospital was scheduled to start by Week 24 (July 13, 2010). It has now been decided due to infrastructure cost constraints, sustainability concerns and new HHS regulations that this will not be implemented. *Contract deliverables which have been significantly modified include:*

- *Develop operating principles and procedures for FFPE tissue demonstration biorepository.*
- *Arrange FFPE tissue block collection and transfer from all participating hospitals to FFPE tissue biorepository at UCHC.*
- *Prepare interim report documenting findings from the FFPE tissue demonstration biorepository project, including cost estimates (due by Week 44 at the latest, November, 30, 2010).*

The report is now considered to be part of the Draft Final Report. Brief descriptions of the challenges involved with this project are contained in Sections 100, 400, 600 and 800. Appendices 8000 and 9000 will apparently contain the IRB and some operating procedures.

*Therefore, we see the CSR and FFPE Projects to have been implemented on a very limited basis with a statewide focus now on the ATA Project. The reports will not be individually prepared and submitted, but limited in scope and subsumed in the Final Project Report.

The third project is the Statewide Virtual Biorepository (VB) (referred to now as Accelerated Tissue Access, or ATA). Issues and requirements specific to an ATA program were discussed at the Advisory Meeting I and will continue to be discussed at the second meeting. Originally, a special panel of stakeholders was to convene to develop and review a draft of a statewide virtual biorepository C*ommon Agreement White Paper*. An interim paper was to be submitted by Week 44. It appears that this is now part of the Draft Final Report Sections 100, 400 and 600 and Appendices 8000 and 9000 in a limited form. The *White Paper*, a significant deliverable, originally had been designated a four month time period for development.

*Therefore, the ATA Project continues as the primary demonstration project. Its progress will be further evaluated after the second meeting of the Advisory Panel. The White Paper, as with the other interim reports, will not be a free-standing report, but subsumed in the Final Project Report.

Summary

The Statewide Tumor Tissue Biorepository Feasibility Study and Lung Tissue Biorepository Demonstration Project are nearing their extended completion date of December 31, 2011. The second and final Advisory Panel meeting will be scheduled in November, 2011. A Draft Final Report, submitted on Oct. 10, 2011, outlines progress to date and proposed modified contracted project deliverables. Both the CSR and FFPE demonstration projects have been significantly limited to projected cost and logistical constraints. The draft Feasibility Study Interim Report and the three Demonstration Project Interim Reports, originally designated as separate reports, have been submitted as part of the Draft Final Report in limited forms and with limited review of stakeholders. These submissions deviate significantly from the original project deliverables and associated timelines.

The successful completion of the second Advisory Panel meeting and the timely inclusion of its commentary into the Feasibility Study Report and Final Project Report will be critical to successful completion of the modified biorepository project.