

Memorandum

To: Dr. Lou Gonsalves

From: Dr. Anne Betzner, Dr. Ann Wendling

Date: 6/17/11

Re: Progress Evaluation of the Connecticut Biorepository Project

This memorandum assesses the progress of the *Statewide Tumor Tissue Biorepository Feasibility Study and Lung Tissue Biorepository Demonstration Project*. 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. PDA is assessing progress on the feasibility study and demonstration projects based on the timeline outlined within the original work plan. Milestones and deliverables are listed and their scheduled completion dates are determined by the number of weeks from the inception of the project. The contract was fully signed and executed on January 26, 2010, so progress on the timeline is judged from that date. We recommend that the UCHC develop an updated timeline in the work plan to reflect the contract extension completion date of December 31, 2011 to facilitate grants management.

Feasibility Study:

The state-wide surveys of Connecticut hospital pathology departments and IRBs have been completed and initial analysis has been performed, but not submitted in report form. The original timeline for the submission of the Final Report of Survey Findings to DPH called for a latest due date at 20 weeks from Project Inception, or June 15, 2010. Significant progress has been made on this deliverable; however, as the Final Report of Survey Findings has not yet been submitted, this deliverable is approximately one year overdue.

The Advisory Panel meetings, up to three, were to be completed by Week 24 or July 13, 2010. Finally, in May 2011, agenda submissions, originally scheduled by Week 14 or May 4, 2010, were submitted and indicated that two meetings will be held. At this time, the majority of attendees have been identified and the initial meeting is anticipated in July 2011. The completion of the set of Panel meetings is a critical step upon which many other deliverables of the project depend. These include establishment of principles and procedures and outstanding issues for the Demonstration Projects, most notably the Statewide Virtual Biorepository (VB) (referred to now as Accelerated Tissue Access, or ATA). In summary, some progress has been made on this set of deliverables; however, they

are currently about one year overdue. The amount of time the deliverables are late will continue to increase until the meetings are completed and subsequent reports are submitted.

The work plan also calls for two reviews of the Interim Feasibility Study Report by the Advisory Panel and subsequent comment by External Reviewers prior to submission to DPH, originally scheduled by Week 26 (July 27, 2010). This deliverable is approximately 10.5 months overdue. To date, there is no apparent progress on this deliverable. Until it is submitted, the amount of time it is overdue will increase.

Demonstration Projects:

The establishment of a Regional IRB, CICATS, with several area hospitals and community research groups has facilitated initial progress in all three types of demonstration projects. A draft IRB package was submitted to CICATS in late May, 2011. There is no comment in the latest report regarding anticipated review or approval date. Revised IRB protocols for final approval by all three participating hospitals were to be circulated by Week 18, or June 1, 2010. Although the IRB process has changed with the establishment of the regional IRB, the IRB submission was approximately one year overdue.

Significant progress has been made in implementation of the **Prospective Collection and Storage of Fresh-Frozen Tissue (FFT) and Serum (Blood) Project** at UCHC, but Hartford Hospital and a third participating hospital, yet to be finalized, have not yet begun implementation which was scheduled for Week 26 at the latest (July 27, 2010). Similarly, the implementation of the **Physical Biorepository of Formalin-Fixed Paraffin-Embedded (FFPE) Tissue Project** at Hartford and a third hospital was to start by Week 24 (July 13, 2010). Implementation is already over 10 months late and the overdue time continues to increase. Interim reports, subsequent to implementation, including cost figures are estimated to take 4-8 weeks to prepare prior to submission to DPH. These were scheduled for submission by Week 44 at the latest (November, 30, 2010). It is anticipated that the reports will be at least 10 months late since the implementation at two of the three hospitals is delayed by over 10 months, as noted above.

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 will be discussed at the Advisory Meetings. Criteria for additional partner hospitals, and the number thereof, to join UCHC and HH in the project are yet to be determined based on hospital surveys and Feasibility Study findings. Operating principles and procedures will be developed based on the requirements identified in the statewide surveys of hospitals and the findings from the Feasibility Study. A period of 20 weeks, from weeks 24 to 44 (July 13, 2010 to November 30, 2010), has been allotted to draft a Common Agreement White Paper to be submitted as a deliverable to DPH. UCHC has reported in quarterly updates that the paper is early in development, however multiple stakeholders have yet to be identified and invited to participate. These may include various entities (identified in Section B.III.3 of the work plan) with an interest in contributing to, utilizing and/or overseeing a statewide Virtual Biorepository. If work on the white paper were to start immediately (June 14, 2011), it is

expected the white paper would be due October 25, 2011. However, it is unlikely that the white paper will be started immediately, as the ATA is not yet fully determined. Given that the end of the second and final contract extension is December 31, 2011, it is possible that less than 20 weeks will be available for the contracted vendor to perform this task. Swift action on a final determination of the ATA and planning now are critical to ensure that the white paper will be completed at a high level of quality by December 31, 2011.

Summary

Currently, no contracted deliverables are fully completed, with the exception of the original work plan. The Feasibility Study Interim Report and three Demonstration Project Interim Reports have only been outlined. Although the project has received an approximate one year no cost extension, all current activities are significantly behind even this expanded time scale.

Evaluation of project flow determines that activities considered essential driving factors for successful and on time project completion are:

- Completion of the Entire Set of Advisory Panel Meetings (currently determined to be two)
- IRB Approval from CICATs
- Successful Implementation of Demonstration Projects at Hartford and a third hospital

Their timely completion in the near future is necessary to allow appropriate and sufficient time for development of the interim reports and the Common Agreement White Paper by the end of the project extension. In particular, the White Paper, a significant deliverable has been designated a four month time period for development. There are concerns that the Common Agreement White Paper will not be completed by the end of the contract extension, unless swift progress is made on all remaining deliverables.

Finally, PDA recommends that UCHC update the timeline of the work plan to reflect the no cost extension ending December 31, 2011 so that future activities may be assessed based on realistic dates of completion.