Minutes from Call Oct. 3, 2011

Attendees
Richard Everson, Helen Swede, Rajni Mehta, Lloyd Mueller, Cathryn Phillips, Lou Gonsalves

Note: Italicized activities are contracted activities that will apparently not be accomplished.

Feasibility Study:
There seemed to be ambiguity regarding the intent of the Interim Feasibility Study Report to be reviewed twice by the Advisory Panel with subsequent comment by External Reviewers prior to submission to DPH. This was originally scheduled by Week 26 (July 27, 2010), but there was comment by UConn that this was thought to be a draft of the final report. *It appears that this interim report will now possibly be rolled into the Final Report. If it is submitted separately, it is unlikely to have the level of review stated above and included in the contract.* A detailed Table of Contents and timeline for remaining anticipated activities are now promised by Oct. 10, 2011. These include establishment of principles 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).

Demonstration Projects:
The establishment of a Regional IRB, CICATS, with several area hospitals and community research groups had facilitated initial progress in all three types of demonstration projects. A draft IRB package was submitted to CICATS in late May, 2011. There was no comment in the latest report regarding anticipated review or approval date. It has now been decided after feedback received at the first Advisory Panel Meeting to continue with two of the projects, the ATA and limited FFT projects.

Some progress has 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 will continue on a small scale at UCHC, Hartford, and? St. Francis. This is essentially self-sustaining at this time. *An interim report on this project was scheduled (per contract) to be submitted to DPH by Weeks 40-44. It appears that this will not be submitted.*

*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 (requiring all DNA tissue to be considered human subjects research) that this will not be implemented. Contract deliverables which will not occur 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 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 further discussed at the second Advisory Meeting to be scheduled the week of Oct. 24 or Oct 31. Criteria for additional partner hospitals, and the number thereof, to join UCHC and HH in the project are yet to be determined. It was decided that it is probably feasible in the limited time remaining to develop a protocol and submit to CICATs, Yale and perhaps one other IRB by Dec 21, 2011. *Originally, a special panel of stakeholders was to convene to develop and review a draft of a statewide virtual biorepository common agreement white paper. An interim paper was to be submitted by Week 44. It appears that this panel will now be the Advisory Panel and that the interim report will be rolled into the Final Report*

Advisory Panel Meeting II- Week of Oct 24 or 31

The focus will be to provide feedback on ATA model and its sustainability. The meeting will be facilitated by Linda Miranda. An anticipated contentious issue is the possible role of pharmaceutical funding. Other agenda items are included on the draft submitted by Dr. Everson. *It was noted that educational activities may need to be dropped due to lack of time.*

MEETING 2: REACHING FOR CONSENSUS

1) New Issues a) Update on NCI RTR Program, Grant Requests b) NIH proposed changes in Guidance on Human Research Protection **c)** Connecticut State change in retention of medical records (10 Years): impact on cancer patients, RTR (may not have case studies available) **d)** Other		
2) Further Description ATA and RTR Options ATA - KEY ISSUES a) Request waivers of consent vs propose obtaining consent – ATA, RTR b) Other		
3) Timing for Initiating ATA and RTR a) ATA - Immediate b) RTR – Request Funding from Bioscience Connecticut c) RTR – Determined by magnitude of demand for samples.		
4) Sustainability Considerations a) NIH/Grant Funding b) Molecular Diagnostics **c)** Pharmaceutical d) Biorepository Consortia		Lisa Miranda
5) Reaching Consensus on ATA and RTR Options **a)** ATA - Request waivers of consent vs propose obtaining consent **b)** RTR Request waivers of consent vs propose obtaining consent		
6) Education a) Public b) Hospital c) Community **d)** Other		
WRAP-UP		