Memorandum

To: Dr. Richard Everson, Dr. Helen Swede, Rajni Mehta

From: Dr. Anne Betzner, Dan Kavanaugh, Dr. Dean Troyer, Dr. Ann Wendling

CC: Dr. Lou Gonsalves, Dr. Lloyd Mueller, Dr. Cathryn Phillips, Barbara Walsh

Date: 8/25/10

Re: Biorepository Feasibility Study

Feedback on Survey of Hospital Pathology Departments

This memorandum provides comments and recommendations on the pathology cover letter and survey. Recommended changes in the cover letter are tracked in the attached cover letter document. Minor clerical changes and comments in the survey may be found in the attached survey document. Comments and suggestions on survey content may be found below. Several additional questions are recommended to better understand each institution's depth of experience with clinical studies and its financial and staffing resources that would be available for the biorepository project.

Question 1: There is no mention of total number of patients or tumors. Getting a percentage of cases gives no indication of volume of tissue to be expected.

Question 2: Current and previous year statistics would be more helpful than information prior to and after January 1, 2000. Although these data are important, current cases and trends would give a better indication of future access to tissue. This reflects changes in biopsy techniques and diagnostic trends.

Question 4: Some reference to a recognized standards agency should be included here such as ISBER or AATB research tissue standards. This will be helpful in establishing the long term basis for agreement among such a large number of institutions.

Question 11 is missing

Questions 14 and 15: Your questions imply that you are considering accessing data from hospitals directly through their databases. Do you think this will be possible with hospitals' confidentiality policies or is it more likely hospital data will need to be keyed in and sent securely to the biorepository?

Questions 16 and 17: This seems to imply that you are either using or plan to use epath; if this is so it might eliminate some confusion to so state.

Question 18: Is there some legal distinction between using specimens from CT residents and non CT residents?

BIOREPOSITORY OPTIONS: The question of coordinating IRBs from many institutions has to be seriously addressed to avoid later confusion and bureaucratic delays.

Option 1: RESIDUAL TISSUE REPOSITORY: Again reference to some objective standard such as ISBER or AATB might help in facilitating agreement among institutions by providing general guidelines to be considered. The same is true of Options 2 and 3 as well. This will by no means eliminate all individual institution preferences, but may provide a basis for discussion of differing opinions and policies. In addition, it may provide context for arbitration.

Recommended Additional Questions

Additional Question 1: Does your lab have the funding and personnel time to identify, collect, prepare and send specimens? Yes No Don't know / not sure
Please comment specifically on any additional resources you may need.

Additional Question 2: Who in your hospital would be responsible for securely and confidentially accessing and conveying clinical data on these samples? (select all that apply)

Drop down options:
□ Tumor registry personnel
□ Pathology lab personnel
□ Clinical research lab personnel
□ Medical records department
□ Other (please specify)_____

Additional Question 3: Would you expect to be compensated to retrieve specimens and/or retrieve clinical data elements required for the biobank? Yes No Don't know / not sure
Please comment specifically on any expected compensation.

Additional Question 4: Does your institution participate in clinical research studies sponsored by drug or diagnostics companies or other funding agencies such as the National Institutes of Health or the National Cancer Institute? Yes No Don't know / not sure____

If yes, check all that apply:
□ We have personnel such as clinical research associates who function as co-investigators for these types of clinical studies.

□ We have personnel who have overseen clinical trials, preparation and submission of institutional review board protocols, and retrieval of clinical data elements.

□ We have personnel who have participated in clinical studies which require retrieval and annotation of tissues such as for a clinical trial of a new drug.

If you have any questions, please don't hesitate to contact us.

Attachments:
Cover Letter with tracked changes and comments
Survey with tracked changes and comments