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Breast cancer cell; istockphoto.com image

## A Controversy on the Breast Cancer Symposium Podium: Mammographic Screening, Overdiagnosis, & Tumor Regression

BY RABIYA S. TUMA, PHD

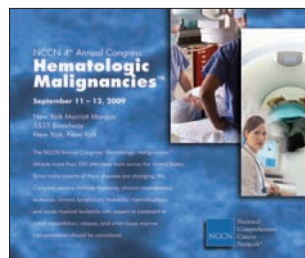
Authors of an oral study reported at the meeting concluded that a substantial proportion of screening-detected cancers would regress if left untreated. The program chairs said they included the paper because they thought a little controversy would spark discussion and a discussant could put the data into context. But, says another expert in a view increasingly shared, that may be oversimplifying a complex issue that the community must start to address.

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### Paclitaxel for Ovarian Cancer: Dose-Dense or Every-3-Week?

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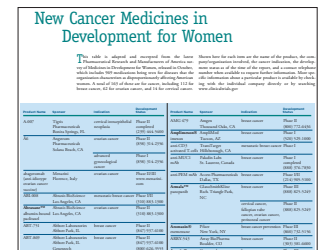
### Supportive Care Treatment Challenges

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### New Cancer Medicines in Development for Women

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caHUB

# New NCI Biobanking Program Aims to Boost Quality of Cancer Specimens

BY PEGGY EASTMAN

**W**ASHINGTON, DC— The American Recovery and Reinvestment Act (ARRA) of 2009 is giving a major boost to the way the

United States collects and stores cancer biospecimens. Of the \$1.3 billion in ARRA funds allocated to the National Cancer Institute, some \$60 million will be used for requests for proposals (RFPs) related to

improving the quality of biospecimens via a new NCI program called the Cancer Human Biobank (caHUB).

Carolyn Compton, MD, PhD, Director of NCI's Office of Biorepositories and

Biospecimen Research, described caHUB as a unique, centralized nonprofit public resource for collected cancer biospecimens of the highest quality.

"We believe that biospecimens are the



basis of molecular classification of disease,” Dr. Compton said, speaking here at the Association of American Cancer Institutes/Cancer Care Administrators Forum Annual Meeting. “Molecular technology promises to transform oncology.”

### Too Siloed, No Standardization

But, she continued, the collection of biospecimens by US cancer centers has up to now been a “siloed system of specimen collection,” with each center collecting, processing, and storing cancer biospecimens differently. “The quality controls used on our biospecimens are variable or lacking. Histologic quality does

Mary Ann Garity/AACI



CAROLYN COMPTON, MD, PHD, Director of NCI's Office of Biorepositories and Biospecimen Research: “In this era of knowledge explosion, if cancer biospecimens are not reliable, we now have the ability to get the wrong answers with unprecedented speed.”

not guarantee molecular quality.”

In addition, the scope and type of patient consent forms differ and materials transfer agreements vary, and so there is an overall lack of standardization in cancer biospecimen banking, presenting “a significant roadblock to translational research,” she said.

In this era of knowledge explosion, if cancer biospecimens are not reliable, “we now have the ability to get the wrong answers with unprecedented speed.”

### 8 RFPs in Next Few Weeks

Asked by *OT* for more specifics on caHUB, Dr. Compton said NCI plans to issue eight caHUB RFPs over the next two months and that the project will be managed by contract.

As for how many cancer centers are likely to be chosen to contribute cancer specimens to caHUB under contract, she said, “The centers will self-select; we’re going to need a core set of institutes to come forward.” She said she expects to have perhaps 10 centers of excellence contributing biospecimens.



Mary Ann Garity/AACI

SCOTT D. JEWELL, PHD, of Ohio State University Medical Center, advised cancer centers to define all common reasons, purposes, and terminology of informed consent, providing a framework across institutions for collaboration, and ensuring that common best practices are used in procurement, processing, and storage of biospecimens and data.”

Dr. Compton emphasized that caHUB addresses a pressing need—in one survey 20% of investigators questioned their data because of the uncertain quality of biospecimens used.

“We know more about the quality of beef in the supermarket” than about the quality of biospecimens, she said. The new caHub program—which was launched earlier this year—aims to brighten that picture by modernizing and standardizing cancer specimen biobanking and boosting the quality of samples available for study.

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→ **caHUB**

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“If we had had caHUB at the beginning of the Cancer Genome Atlas, it would have helped,” she said. The Cancer Genome Atlas Project (TCGA) of the National Institutes of Health, which has more than 24 participating institutions, is a large-scale collaborative effort to characterize the genomic changes that occur in cancer.

TCGA evolved from a 2006 pilot project; and this past September NCI and NIH’s National Human Genome Research Institute (NHGRI) announced that TCGA will work to produce comprehensive genomic maps of at least 20 types of cancer over the next five years.

**Roswell Park**

Other speakers at the AACI meeting described their efforts to improve cancer biospecimen banking at their own institutions.

“Our goal was to create a uniform, efficient, and effective process for obtaining and banking remnant biospecimens for use in future research,” said Camille Wicher, Esq., RN, MSN, Vice-President for Corporate Ethics and Research Subject Protection at Roswell Park Cancer Institute.



Mary Ann Gately/AACI

CAMILLE WICHER, Esq., RN, MSN, of Roswell Park Cancer Institute: “Our goal was to create a uniform, efficient, and effective process for obtaining and banking remnant biospecimens for use in future research...The institution undertook a wholesale revision of its tissue procurement facility protocol, which entailed receiving the contributions and buy-in of all stakeholders.

She described how Roswell Park undertook a wholesale revision of its tissue procurement facility protocol, which entailed receiving the contributions and buy-in of all stakeholders. The new process includes clinical databases to provide information for translational research purposes, recognition that biospecimens include more than whole tissue (sputum and blood, for example), and an updated, upfront informed consent obtained at patient registration that meets legal, ethical, and policy requirements.

Ms. Wicher said Roswell Park wanted a protocol/consent process that would:

- Allow investigators to collect just one consent for remnant biospecimens.
- Facilitate the collection of informed consent at the time of patient registration.
- Ensure that the consents are effective for every procedure undergone at Roswell Park.
- Allow the linking of biospecimens to clinical databases at Roswell Park.
- Allow for the distribution of biospecimens (human tissues or macromolecules) to investigators there as well as external customers.
- Allow for the distribution of clinical data linked to those biospecimens.

“Every step of the way there have been some kinks that we’ve had to work out,” said Ms. Wicher, noting, though, that Roswell Park is moving forward to make the new protocol/consent system as seamless as possible.

**Ohio State**

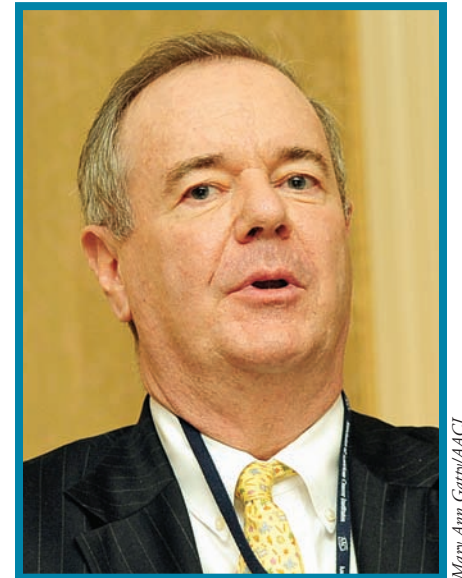
Scott D. Jewell, PhD, Associate Professor in the Department of Pathology at Ohio State University Medical Center, said his institution went through an updating of its biorepository processes according to NCI best practices in 2008.

Dr. Jewell, who is also an Associate Director of the OSU Comprehensive Cancer Center for Biorepository and Biospecimen Resources, noted that a universal informed patient consent process for biospecimens is efficient and cost-effective, but that if different cancer centers use different collection methods, these differences can limit collaboration on research. Genetics is still a question mark in terms of the scope of consent needed for future biospecimen research, he noted, and confirmed Dr. Compton’s observation that US biospecimen banking has traditionally not been standardized.

Dr. Jewell advised cancer centers to “define all common reasons, purposes, and terminology of informed consent,” providing a framework across institutions for collaboration, and to “ensure that common best practices are used in procurement, processing, and storage of biospecimens and data.”

**M. D. Anderson**

Paul Papagni, JD, Executive Director of the Office of the Vice President for Clinical Research at the University of



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PAUL PAPAGNI, JD, of M. D. Anderson, described efforts there to migrate satellite tissue banks into one central biorepository and devise a comprehensive informed consent process.

Texas M. D. Anderson Cancer Center, described efforts at his institution to migrate satellite tissue banks into one central biorepository, and efforts to come up with a comprehensive informed consent process.

M. D. Anderson, he said, has an electronic front-door consent process in English as well as Spanish versions. Mr. Papagni urged his listeners to consider the problems and issues that can arise with informed consent, which, he said, can be posed as the following questions:

- What if the subject refuses a protocol-specific consent even if he or she signed a front-door consent—which takes precedence?
- How specifically must anticipated future research use of collected biospecimens, such as genomic uses, be described?
- What happens to tissue samples used in a study when that study is over?
- How carefully is a waiver of consent documented?
- What process is used to track consent revocation?
- What happens to pediatric consent once the subject reaches the age of majority?

“The devil is in the details,” Mr. Papagni said. “You need to watch your trial protocols to make sure the detail is there.” ☐



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