THE CANCER LETTER

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Advisors Tell NCI To Rethink Contracts For Cooperative Group Tissue Banks

Coming to the defense of the clinical trials cooperative groups, an NCI advisory committee told the Institute to reconsider a plan to use contracts rather than grants to fund the groups' tissue banks.

The cooperative groups and their tissue banks are funded through U10 cooperative agreements, a type of grant. Changing the funding mechanism for the tissue banks to contracts could compromise the groups' control of the specimens, the NCI Board of Scientific Advisors concluded at a meeting Nov. 13.

At a time when the NCI leadership and the National Dialogue on Cancer are preparing plans to overhaul the system for conducting clinical trials and collecting specimens, BSA members chided the Institute for failure to discuss its proposed $47.8 million, five-year tissue bank

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In Brief:

Weinberg Wins AACI Award; Foundations Honor Bernard Fisher; NIH Offers Loan Repayment

ROBERT WEINBERG, known for his discovery of the first human oncogene and the first tumor suppressor gene, was honored with the 2003 Distinguished Scientist Award from the Association of American Cancer Institutes at the AACI meeting last month in Washington, D.C. Weinberg is the Daniel K. Ludwig Professor for Cancer Research at Massachusetts Institute of Technology and a founding member of the Whitehead Institute for Biomedical Research. AACI also honored with its 2003 Public Service Award **Sen. Arlen Specter**, chairman of the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee, and **Sen. Tom Harkin,** ranking member of the subcommittee. . . . **BERNARD FISHER** received the Spirit of Life Award, given by the International Spirit of Life Foundation, "for his exceptional achievements in the field of breast cancer research." He also received the Jill Rose Award from the Breast Cancer Research Foundation, "in recognition of his outstanding contribution to breast cancer research, for his exploration of the biology of cancer, and for his role in altering the character of modern breast cancer treatment." Fisher is a Distinguished Service Professor at the University of Pittsburgh and a founding member and former chairman of the National Surgical Adjuvant Breast and Bowel Project. . . . **NIH** awarded $63.3 million in student loan repayment contracts to 1,200 health researchers in the U.S. in fiscal 2003. Applications for 2004 awards are available at www.lrp.nih.gov. The application deadline is Dec. 31.

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Advisors Urge NCI To Talk To The Group Chairmen

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contracting plan with the cooperative group chairmen before bringing it to the board meeting.

"You need input from the people who are currently doing the work," said BSA member Thomas Curran, chairman of developmental neurobiology, St. Jude Children's Research Hospital. "Some of the cooperative groups have done a good job. There are good studies coming out, and maybe we can learn from their wisdom and maybe export some of the ideas they have developed.

"In solving a complex engineering problem like this, it's usually always better to go bottom-up than top-down," Curran said. "If you try to pull this unique database structure from the top down, taking account of all of the issues that everybody needs to address, you will never get there. You will get bogged down in details. It's very complex to make things work together.

"If, instead, you build from the bottom up, each group may already have a solution, and the key issue is, how can you port that solution into the common network," Curran said. "It's a different kind of engineering challenge, it's a big challenge, but in a sense, it's more soluble than trying to fix everything overall from the top."

The BSA voted 17-0, with one abstention, to approve the proposal in principle, but send it back to the NCI Executive Committee for discussion of the funding mechanism. A subcommittee of the BSA will consider the EC decision and possibly bring it to the BSA for another vote.

Though the tissue banks have been funded through a fragile patchwork of cooperative agreements, philanthropy, and industry grants, group chairmen and their supporters on BSA saw a Trojan horse in the NCI offer of a five-year contract.

"The immediate reaction of the groups to a contract is negative," BSA member Richard Schilsky said to **The Cancer Letter**. "NCI needs to clearly articulate the pros and cons of the contract mechanism versus a cooperative agreement.

"There is no evidence at this point that what NCI wishes to accomplish can't be accomplished with a cooperative agreement," said Schilsky, chairman of the Cancer and Leukemia Group B, after abstaining from the BSA vote on the proposal.

NCI will present the proposal to the cooperative group chairmen at their semi-annual meeting scheduled for Dec. 12 in Bethesda. The EC discussion is scheduled for Dec. 16, and NCI plans to conduct a teleconference with the BSA subcommittee soon thereafter, said Ellen Feigal, acting director of the NCI Division of Cancer Treatment and Diagnosis.

Control of the Data

Contract funding would separate the tissue banks from the rest of the cooperative group programs, giving NCI greater control over the specimens and the data, group chairmen say.

If the groups become NCI contractors, they may be subject to the provisions of the Freedom of Information Act. The issue of FOIA applicability to group data emerged in 1994, following the finding of scientific fraud by an investigator involved in the National Surgical Adjuvant Breast & Bowel Project.

At that time, to conduct an audit, NCI obtained NSABP data from several trials. The Chicago Tribute was able to get the data by filing a FOIA request.

Also, NCI conducted a field audit of about 1,500 patients enrolled in B06, the landmark trial comparing mastectomy to lumpectompy with and without radiation. The Institute gave the data to a contractor, the EMMES Corp., and declined to provide these data to the Tribune. However, the newspaper filed a suit, and the court held that because the data had been generated by NCI, they were government data, ordering EMMES to turn over the materials.

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Group chairmen have other reasons to be wary of NCI's intentions. While the cancer centers, Specialized Programs of Research Excellence, and training programs received double-digit funding increases in fiscal 2003, the Institute planned only a 3 percent increase for the groups.

Then, several months into the fiscal year, NCI told the groups not to expect even that. At the same time, NCI Director Andrew von Eschenbach said he would appoint a panel to conduct another "comprehensive review" of the clinical trials system.

In the past eight years, the group system has been reviewed twice by NCI-appointed panels, and recommendations for change included increased funding and reduction and centralization of regulatory burdens.

Last June, NCI officials told the group chairmen that von Eschenbach declined to provide funds specifically to support the tissue banks, despite strong advocacy by the Institute staff.

At the time, Sheila Taube, director of the Cancer Diagnosis Program, told the group chairmen that the staff was "trying to think of more creative and innovative ways to provide stable funding for the tissue bank effort that doesn't get plowed into the cooperative group [funding] line" (**The Cancer Letter**, July 11).

Meanwhile, von Eschenbach and the National Dialogue on Cancer announced a major initiative to create a "National Biospecimen Network." The role of existing resources was not clear in a draft of the network proposal (**The Cancer Letter**, Aug. 8).

Late in fiscal 2003, the groups received a $4 million supplement to their base funding of about $269 million to help support the banks, NCI sources said.

Goal to Create "A More Effective Resource"

"Investment in and assuring access to high-quality specimens that are linked to demographic, treatment, and long-term clinical outcomes is critical if the NCI is going to reach the 2015 goal of eliminating suffering and death from cancer," DCTD Director Feigal said in her remarks to the BSA introducing the concept statement.

"The clinical trials cooperative groups have contributed enormously to advances in treatment of the cancer patient," Feigal said. "This has been accomplished through the development and conduct of well-designed, large, multi-center clinical trials. Within the context of these clinical trials, investigators over the years have collected specimens which are tightly linked to very valuable information, [including] treatment, and long-term clinical outcome. This can be a source of tremendous value to help answer a wide variety of clinical questions. With the rapid advances in technology and science, it's within our grasp in the ensuing years to develop more diagnostic markers, predictive markers, a whole variety of questions that we can try to answer that would actually be useful to the patient."

The purpose of the proposal is to try to make the tissue banks "a more effective resource for the research community," Feigal said.

"We wanted to hear from the board, first, do you buy into the basic premise that these, indeed, are valuable specimens for research?" Feigal said. "If you do, then are the objectives that have been articulated in the proposal appropriate to go forward with, and is the approach...the most objective way to go forward?"

Presenting the concept, Roger Aamodt, chief of the Resources Development Branch in the Cancer Diagnosis Program, said the contracts would provide stable funding to the nine tissue banks and would help them implement "best practices" and standard data measurements, and provide specimens and data to investigators who are not part of the groups.

"These are unique resources, there is a critical need for specimens with treatment information and careful long-term follow-up," Aamodt said. "There is a question of access. There have been researchers who said it was difficult for them to get access to the cooperative group banks, and there are a number of reasons for that, primarily because the banks were never sufficiently funded to provide that service."

The contract would require the groups to work with the NCI Tissue Expediter to try to match investigators with available specimens.

An Intergroup Specimen Banking Committee has evaluated best practices and set up a uniform process for access to the specimens. That committee met in September 2001, but NCI has not convened the committee since. Under the contract, NCI would reconvene the committee as the primary oversight for the tissue banks, Aamodt said.

"It should be made very clear that we are not using the contract mechanism to try to get control of the group banks or to try to own the specimens or the data," Aamodt said. "These are all things that belong to the groups, that have been created by the groups, and which are very important to the groups. What we are trying to do is create a partnership with

the groups in order to improve the processes that the groups are using, to cause more interaction between the groups, and to improve the utilization."

Aamodt said NCI would like the groups to agree to "more closely coordinate their activities and work on widening the standardized researcher application procedures—in fact, what we would like to see is one single point of access."

Concept Reviewers Puzzled

BSA members who reviewed the concept said the group tissue banks deserve additional support.

"The value of the cooperative group tissue banks should be fairly self-evident," said BSA member Michael Link, chief of the Division of Hematology, Oncology and Stem Cell Transplantation, Stanford University School of Medicine. "I ran a leukemia bank for 10 years and thought it was a great resource. The banks were developed on the fly and were not adequately supported, and despite this, they have the best annotated tissue resources because there are patients on trials.

"In addition to the clinical data and tumor characteristics, I think one of the things that's forgotten sometimes, is that the specimens themselves have undergone additional testing in reference labs, so there's actually a lot of stuff that's known about these tissues," Link said.

The proposed funding might be too low, Link said. "This is kind of a Band-Aid, it's $9 million [in first-year funding] to replace $8 million, that doesn't sound like an enormous increment, so maybe it should be reconsidered."

However, Link said, he still did not understand why NCI proposed to fund the banks through the contract mechanism.

"There is a stipulation in this proposal that separating the funding and oversight of the cooperative group specimen banks from the oversight of the treatment trials will facilitate the quality and availability of the specimens, and I'm not sure I understand why that is actually true," Link said. "I would think the opposite, in the sense that the strength of collecting the well-annotated tissues derive not from the specimens themselves. What really is the strength is the science that's derived from them. When you are trying to defend a cell bank initiative at a site visit, you don't try to say you've got a lot of specimens. You have to say what publications and what impact they had. Separating those two oversights, I don't know if it's good or bad, but it wouldn't have been intuitive to me that that was a great idea.

"Why not give the same funding as a competitive supplement to the cooperative group grant, to go straight to where the rubber meets the road?" Link said. "The deliverables could still be delivered, and some of the goals like the common procedures could be achieved, and it would make it clear where control of the resource lay."

Curran said the proposed contract "would not be the solution to the problem that we have to acquire fresh, frozen solid tumor tissue." The purpose of the banks is to "collect tissue blocks, cores, slides, fixed sections," and other mechanisms will need to be created to support "protocol-specific acquisitions for studies," he said.

"That raises the issue of mechanism, so I'm not convinced that the contract mechanism is the way to go," Curran said. "[Contracts] tend to be a touch inflexible, because there are real government rules and regulations that come along with them. Maybe in this circumstance, flexibility should be paramount, because we have many different disease subsets, different cooperative groups, different organizations already doing quite a lot of this work."

Curran also questioned the wisdom of separating the funding and oversight of the groups and the tissue banks between NCI's Cancer Therapy Evaluation Program and the Cancer Diagnosis Program. "It kind of sounds logical, but essentially you are building another layer of bureaucracy," he said.

"It's very important to establish stable funding [for the banks], but I hope there would be an easier way to do that than to try to fit everything into a contract," Curran said.

Schilsky said he didn't know the details of the proposal until he received the BSA board packet from NCI a few weeks before the meeting.

"I did have the opportunity to mention the proposal to some of my fellow group chairs, and the reaction from them, not knowing any of the details, ranged from disappointment to strong opposition.

"Those feelings were based exclusively on the proposed funding mechanism," Schilsky said. "The need is clearly there. We are very appreciative of the Cancer Diagnosis Program's support for the group banking system, but there is a lot of concern about the contract as the proposed funding mechanism."

Schilsky said the board packet always includes pages of review criteria for grants and contracts.

"I would point out that the justification for

contracts as the funding mechanism are the following: 'to support NCI-directed research activities; for projects that require direction by NCI staff; and contracts are to be used where NIH intends primarily to obtain goods, services, research studies, surveys, systems, or property for the direct benefit or use of NIH.' Clearly, we don't feel any of those justifications apply in this particular case," Schilsky said.

"The groups began the banks in the 1980s and early '90s on their own initiative using the funds cobbled together from a variety of sources," Schilsky said. "The supplements we had over the years certainly helped keep them going. Stable funding is necessary.

"The board should understand that the group tissue banks are part of an integrated system, the Cooperative Group Program that includes not only the banks, but also institutions, pathologists, statistical centers, reference laboratories, and so on. There is a lot of concern about extracting the banks and funding them by a separate mechanism."

The Intergroup Specimen Banking Committee is "very effective," but NCI has not convened it since 2001, "despite urging by myself and others to do so," Schilsky said. A report developed in late 2001 by the committee about standardization has never been distributed to the group chairmen, he said.

"This is a very important initiative that is well-intentioned, but the funding mechanism should be reconsidered," Schilsky said.

The reviewers also questioned NCI's contention that the groups should provide greater access to the banks.

—"The specimens are collected as part of the clinical trials and some of them are collected with secondary goals in mind, so it's very important to have scientific oversight of the tissues, how they are used, who you collaborate with," Link said. "Perhaps the reason potential collaborators have found that they have not been received warmly or turned down is the fact that there is another investigator who already has proposed the same project.... Certainly, the design of the study, what kind of controls are used, and the actual analysis of the data, particularly in those studies that establish prognostic criteria, this should be properly the purview of the cooperative group investigators and statistician, and these are the recommendations of the Intergroup [Specimen Banking] Committee, which I sat on. It's pretty important that those remain the rules of the road."

—"If access to specimens is difficult, there may be reasons for that," Curran said. "Maybe it's good to revisit those problems, to say, which of the groups has solved this problem well, and which of them have special reasons that you can't simply allow open access."

—"The notion of limited access is not a real issue," Schilsky said. "We published a paper in Cancer Research describing the CALGB repository for all the world to see. We had one investigator express interest in working with us."

Feigal suggested that the board approve the concept, leaving it to the group chairmen to select the funding mechanism at their upcoming meeting.

Link proposed that the funding decision be negotiated with the group chairmen and then finalized by the BSA.

However, BSA Chairman Frederick Appelbaum, director of clinical research at Fred Hutchinson Cancer Research Center, said he didn't want the board to "get in the habit of leaving things half-done and finalized by email."

BSA member Kenneth Kinzler, professor of oncology at Johns Hopkins, suggested a vote on the contract mechanism.

Feigal opposed an up-or-down vote. "This has to be done as a team effort with the groups," she said. "It doesn't matter if you approve it, because we won't be able to work with them. I would propose that we modify it, but it's a timing issue."

Funding contracts for fiscal 2004 "would be tight," Taube said. "But it would be impossible if done as an RFA, so there wouldn't be funding for this year."

"Give them a supplement," suggested BSA member Hoda Anton-Culver, professor and chief of epidemiology, University of California, Irvine.

The BSA voted to table the discussion until the next day, Nov. 14. At that session, Paulette Gray, director of the Division of Extramural Activities, said that under federal regulations, the NCI Executive Committee must select a funding mechanism.

She suggested that the board approve the concept in principle, send it to the EC, and appoint a subcommittee to review the decision.

Anton-Culver made the motion to approve that plan, adding that if the subcommittee agrees with the EC, the concept will be considered approved, and if the subcommittee disagrees with the EC, the concept will come back to the BSA for discussion.

Appelbaum appointed himself and three others to subcommittee: Neil Clendeninn, of Clinical Pharmaceutical Consulting; William Hait, director of

the Cancer Institute of New Jersey; and Susan Horwitz, Falkenstein Professor of Cancer Research, Albert Einstein College of Medicine.

The text of the concept statement follows.

Support for human specimen banking in the clinical cooperative groups. Concept for an RFP, first-year funding $9 million, total $47.8 million over five years, nine awards.

This initiative is designed to ensure the quality and improve the availability to the research community of the NCI Clinical Cooperative Group human specimen resources. The Groups' collections are unique and critical as they are the only source of specimens and data from patients treated uniformly on phase III clinical trials and followed carefully for multiple clinical outcomes. Access to specimens with associated high quality clinical, treatment, recurrence and outcome data will be critical to developing and validating the markers needed for diagnosis, prevention and prediction of response to therapy. This will be essential to eliminating the suffering and death due to cancer by 2015.

The advent of powerful molecular technologies and the emergence off targeted therapeutics have opened the door to developing more effective and, in some cases, individualized treatment of patients with cancer. Developing and effectively using cancer interventions based on the comprehensive analysis of critical pathways of cancer development and disease progression will ultimately require access to specimens from patients treated in randomized trials. The Clinical Cooperative Groups are uniquely positioned to provide the high quality specimens and data needed to meet this challenging goal.

The Cooperative Group specimens and data are essential to advancing our understanding of how to diagnose and treat a variety of cancers, but access to the Group specimens has involved complex procedures and has been particularly difficult for researchers not affiliated with the Groups. In part, this has been because the banks have not had sufficient dedicated funding for the infrastructure necessary to prepare and distribute specimens. Coordination was limited due to lack of funds and this has resulted in the evolution of separate, complicated application procedures. The Cancer Therapy Evaluation Program attempted to address these issues by establishing an Intergroup Specimen Banking Committee that was charged with developing policies and procedures that would apply to specimens and data from Intergroup trials. The Intergroup Specimen Banking Committee has developed a set of standardized procedures for collection and storage of specimens. However, there has been inadequate support to ensure implementation of the proposed plans.

The Resources Development Branch of the Cancer Diagnosis Program has considerable experience in overseeing human specimen resources, has the responsibility for coordinating all specimen collection activities of the NCI, and can effectively monitor the operation and utilization of these resources. CDP and CTEP are in agreement that separating funding and oversight of the Cooperative Group specimen banks from the oversight of treatment trials will facilitate implementation of NCI plans to ensure quality and availability of specimens. This shift of responsibility from CTEP to CDP will enable the NCI to effectively coordinate the efforts of the individual Group banks and facilitate the creation of an integrated virtual system of banks all of which adhere to the highest standards for the collection, storage and distribution of specimens. RDB has already developed systems to help researchers gain access to the specimens they need for their research and for marketing the availability of specimen and data collections. These systems can now be effectively leveraged to assist the Cooperative Group Banking System so that researchers will become aware of the availability of the Cooperative Group specimens and the application procedures.

Types of Specimens and data: The Cooperative Group Banks have collected a variety of different specimen types, primarily from patients on phase III treatment trials. These collections include specimens from all organ systems represented in trials carried out by the groups. Seven of the nine banks have collected fresh frozen specimens. All of the banks have formalin-fixed, paraffin-embedded specimens stored as blocks and/or slides. Other specimens, such as blood components, have been collected by some banks. Some of the Groups have developed methods to facilitate the submission of specimens and ensure their quality.

Correlative Studies: The Cooperative Group banks have supported an impressive variety of correlative studies, and a large number of publications have resulted from the use of group specimens and data. While the list is too large to detail here, a few examples illustrate the usefulness of the banks. Specimens from the CALGB leukemia bank were recently used in a study that identified a new prognostic marker by showing that there is a high correlation with adverse outcome in myeloid leukemia patients with the FL T3 gene with an internal tandem mutation and the absence of the wild-type allele, the $FLT3^{ITD/-}$ phenotype. Use of the CALGB solid tumor bank and the NSABP tumor bank have resulted in several studies that demonstrated that patients with HER-2/neu overexpression by immunohistochemistry benefited from intermediate or high dose chemotherapy with doxorubicin. The NCCTG and NSABP have recently published comparisons of the ability of local versus central laboratories to evaluate HER-2/neu in candidates for Herceptin treatment. [A]n exhaustive list of cooperative group studies would require more than 100 pages....

Support: Historically, there has been no specific funding for the Cooperative Group specimen banking activities. These banks have been funded in part by the U10 cooperative agreements that provide the support for clinical trials. The banking activities were expanded using

a patchwork of NCI supplements, industry funds and funding from other sources. It is the patchwork approach that has led to inconsistencies among groups, unfunded mandates and variations in funding that have made it difficult to operate and coordinate the banks.

The Intergroup Specimen Banking Committee was recently asked to recommend levels of staffing, required equipment and necessary supplies to fully support the Cooperative Group banks. They identified the activities necessary for operation of a well conceived bank. These include support and training for staff to collect and ship specimens from the collecting sites to the central banks, staff to oversee receipt of specimens and transfer them to storage at the central bank, pathologic review and histology services. Costs must also include review of requests for specimens and data, retrieval and shipment of specimens to researchers or to return blocks to the collecting sites for legal or diagnostic reasons, costs of equipment and supplies needed to maintain the banks, informatics to track specimens and miscellaneous costs such as maintenance contracts and subcontracts to participating institutions.

Purpose of the RFP: The purpose of this initiative is to create an integrated virtual national specimen bank for Cooperative Group specimens and thereby improve access to their banked specimens and associated data. The proposed contracts would fully support the Clinical Cooperative Groups' banking activities. Contract funding will require that the groups work together to develop consistent collection procedures and quality assurance standards. Separating the banking activities from other group activities will allow NCI to monitor group banking activities and the research projects that are supported by the Groups' banked specimens. The contract will also require that the banks provide data to the Specimen Resource Locator to help the NCI Tissue Expediter refer potential users to the most appropriate group banks.

The Intergroup Specimen Banking Committee proposed, and the Group chairs recently agreed, that Intergroup trial specimens be collected and centralized in the bank of the lead group for that trial. While these changes have only just been implemented, they promise to improve the quality of the banking efforts and the availability of the specimens. Providing contract funding for the banking efforts will allow the RDB to ensure that these changes accelerate and that the Groups adhere to the agreements among the banks. The Groups, in applying for this funding, will be required to provide a plan for coordinating with the other banks and agree to central governance in accordance with the plan developed by the Intergroup Specimen Banking Committee.

The Cooperative Group proposals will be required to address a variety of issues, including: establishing a single common application procedure for use of specimens from the banks; coordination of protocol development and banking of the resulting specimens; collection of the types of specimens that meet the needs of current and emerging technologies; procedures for handling specimens from collection through processing and storage of specimens, to retrieval and shipment to investigators; development of common data structures for banking activities to allow tracking of specimens and determination of availability of types of specimens; improved researcher access to specimens and data; establishing policies for charges to cover the costs of distributing specimens.

Requested Budget: $9 million in the first year to fully fund nine banks. This request is based on our experience with a variety of human specimen resources as well as the results of the Intergroup Specimen Banking Committee estimates of the costs of operating a fully functional and responsive specimen bank.

Current Portfolio Analysis: The Cooperative Group banks provide a unique resource not duplicated by any of the other NCI supported specimen resources. These contracts will provide the support for the infrastructure required to make the Cooperative Group specimens and data more widely available and to ensure the Banks implement the quality control procedures needed for state-of-the-art human specimen repositories.

The "blueprint" of proposed National Biospecimen Network that is being developed by the National Dialogue on Cancer, a public private partnership which includes NCI participants, recognizes that the Cooperative Group Banks may provide an ideal complement to the NBN because of their unique combination of specimens, high quality data including detailed treatment history, recurrence and outcome.

Justification for Use of Contract Mechanism: Contracts are the appropriate mechanism for this initiative because the NCI can define the scope of the work, closely monitor and coordinate the activities, and ensure that the individual banks adhere to the agreements set in place. Use of the contract mechanism will expedite the development of common procedures, quality assurance standards and implementation of systems to improve access to specimens and data. By providing the contract funding to the Cooperative Group Chairs, the NCI will assure that the infrastructure and technology are in place to effectively collect and bank Cooperative Group Specimens in a coordinated manner. It will also prevent duplication of tracking systems and financial systems that would be required if the contracts were awarded to separate banking facilities. Integration of the main Group coordinating centers and statistical centers will be critical to making data available and anticipating the workload.

The deliverables on these contracts will include, but not be limited to, a set of policies for interactions among the banks and for access by the research community to specimens from the banks, common procedures for collecting, tracking, and distributing specimens, reports on activity within the bank, such as numbers of specimens collected, protocols initiated, applications received and investigators served, and interactions among banks.

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