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CSR Draft Report Proposes New Panel To Review Clinical Oncology Research

A draft report by the NIH Center for Scientific Review calls for the formation of two new "special emphasis panels" for the review of clinical grant applications in oncology and cardiovascular research.

The proposed panels would review grant applications for patient-oriented translational research and small clinical trials, the report said. Currently these applications are reviewed by several study sections.

The panels would be created on an experimental basis.

By "clustering" the review of clinical grant applications, CSR would address the long standing concern of clinical investigators that clinical

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In Brief:

NBCC Plans Meetings On Quality Of Care, Potential Environmental Causes Of Disease

THE NATIONAL BREAST CANCER COALITION will hold a series of meetings to define quality of care in breast cancer and set the agenda on issues of potential environmental causation of the disease. NBCC President **Fran Visco** said the meetings are intended to review available evidence, design new approaches and appropriate public policy, and inform NBCC constituency. "We are regularly asked to support pieces of legislation that deal with specific aspects of these problems," Visco said. "It's up to us get beyond this piecemeal approach, bring together the key players, and produce a comprehensive agenda." The NBCC Environmental Policy Summit will be held in Washington Sept. 24-25. *The quality of care meeting* will be held in Phoenix next January, with a follow-up meeting on Capitol Hill a month later. . . . **ARIZONA CANCER CENTER** received a five-year, $500,000 Bristol-Myers Squibb Unrestricted Cancer Research Grant. **Sydney Salmon**, director of the cancer center and Regents Professor of Medicine at the University of Arizona Health Sciences Center, will serve as grant administrator. Receipt of the grant coincides with the opening of a $22.5 million expansion project that adds 30 new cancer research laboratories to the center. . . . **ANDREW VON ESCHENBACH** was named executive vice president and chief academic officer at M.D. Anderson Cancer Center. Von Eschenbach is chairman of the department of urology and holds the Roy and Phyllis Gough Huffington Clinical Research Chair in urologic oncology at M.D. Anderson. He will continue to serve as director of the multidisciplinary Prostate Cancer Research Program at the center.

CSR Proposes Clinical Oncology Study Section

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research does not fare as well as basic research in some study sections, CSR Director Ellie Ehrenfeld said to the CSR Advisory Committee at its meeting Feb. 17.

A recent study found that clinical research does not fare as well as basic science in study sections that do not review a large percentage of clinical grant applications. However, in study sections that review a high proportion of clinical applications, the clinical proposals fare as well as other applications, the NIH study found.

"There is a perception of a problem that is so widespread and it is supported by the data," Ehrenfeld said. "It was time to try to construct a set of proposals to begin an experiment."

The draft report, "Review of Clinical Research in the Center for Scientific Review," was distributed to the Advisory Committee for comment. However, Ehrenfeld called the report "preliminary" and said a final document would be prepared after CSR receives comment from extramural investigators.

Two Additional Panels Proposed

Clustering clinical oncology and cardiovascular grant applications would take care of about half of the clinical grant applications submitted to NIH, the report said.

To handle the clinical applications in other fields, the report proposes the formation of two additional special emphasis panels, one for "human interventions" and one for large multi-center clinical trials, outcomes research, and health services research.

In addition to the new panels, the report proposes that CSR:

—Appoint an ombudsman for clinical research in study sections that do not regularly review a large proportion of clinical grant applications (termed "low-density" study sections).

—Seek opinion from largely clinical study sections on any clinical application that ends up being reviewed in a low-density study section.

—Request outside opinions from clinicians on clinical applications reviewed in low-density study sections.

The draft report does not state how long the proposed panels would be considered experimental or how their success would be measured. Similarly, it is unclear what would happen to existing study sections in clinical oncology and cardiology.

In a presentation earlier this month to the National Cancer Advisory Board, Ehrenfeld said she anticipated a reorganization of study sections in clinical research (**The Cancer Letter**, Feb. 13).

Clinical research is one of many areas undergoing review and reorganization within CSR. Ehrenfeld said an examination of the organization of all study sections has been one of her highest priorities since her appointment as director of CSR (then known as the Division of Research Grants) last year.

CSR recently formed a Panel on Boundaries of Scientific Review to evaluate how decisions are made to establish new study sections and disband existing study sections, Ehrenfeld said to the CSR Advisory Committee.

In addition to clinical research, the center has begun to study how it reviews behavioral and social sciences research, and instrumentation technology development.

"I started work first on clinical research because that's where the most pressure was," Ehrenfeld said. "We are just now beginning to work on behavioral research now that clinical research is reaching closure."

The draft report acknowledges that the review of clinical research is controversial. "It must be

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emphasized that substantial controversy exists within CSR, within the Institutes, and within extramural constituencies about what the problems really are," the report said. "Reaching a satisfactory definition of clinical research has even been difficult."

Impact On Existing Study Sections?

Reacting to the draft proposal, CSR Advisory Committee member Raphael Pollock, chairman of the Department of Surgical Oncology at M.D. Anderson Cancer Center, cautioned against disrupting clinical study sections that are working well.

"There are some what I presume would be very high-density clinical study sections in oncologic research right now, and I'd like to know what their role would be if we were to implement a [special emphasis panel] in clinical oncology," said Pollock, who served on the Experimental Therapeutics 2 study section for four years.

"ET2 is one study section where there is more than one surgical oncologist," Pollock said. "Given that 85 percent of the curability of solid tumors requires surgery, everyone in this room has a vested interest, ultimately, in having surgically-relevant questions asked and answered in a critical peer-review forum.

"How are we going to make certain that as we create a clinical oncology SEP, that [it will not impact] the already effective high-density study sections that have a composition favorable for optimal clinical review?" Pollock said.

"I don't like equating and pooling the small, single-institution clinical trials with the concept of patient-oriented translational research," Pollock said.

Committee member O. Michael Colvin, director of the Duke Comprehensive Cancer Center, said there is a "void" in the review of small clinical trials in cancer. "Most of my colleagues and I gave up a long time ago and went to other venues," he said. "The time involved, the quality of review, and the result, was so lousy that we just gave up. The focus of the review was often methodology rather than how you evaluate the outcome."

Committee chairman Keith Yamamoto, chairman of cellular and molecular pharmacology, University of California, San Francisco, said the problem of review of clinical applications had not been well described. "There is an assumption that a high-density study section is good and a low-density study section is not, and a clinical application referred to a low-density section is mis-referred," he said.

Pollock said CSR needed more data on the problem. "How well do we know that high-density study section review ultimately results in better clinical science?" he said. "We don't know that.

"We are responding to a perception that clinical research doesn't get as effectively reviewed, i.e., doesn't reach fundability via the low-density route as compared to the high-density route," Pollock said.

Ehrenfeld: Problem Described "Ad Nauseam"

Ehrenfeld said grants are referred to study sections based on the subject matter. "Where there is not a large number of grants of a given subject, it gets sent to the study section that deals with that subject area, and at times, it will get sent to a study section in which clinical applications may represent a minority," she said.

"The data that has been provided by an enormous number of studies says that in that situation, defined as the low-density situation, clinical research grants aren't as advantaged," Ehrenfeld said. "I think it's almost obvious.

"I feel like the problem has been described ad nauseam now through many, many reports."

"What the proposal says its, let's look at these grants that are in those low-density study sections and see how can we cluster them," Ehrenfeld said.

In the cardiovascular research Initial Review Group, seven study sections were found to have a low density of clinical applications, Ehrenfeld said. "Let's pool all of those, there is a commonality, they all address cardiovascular problems. Let's reorganize the study sections in that IRG and cluster the clinical applications.

"We can also do that in clinical oncology," Ehrenfeld said.

Committee member Olga Jonasson, director of education and surgical services at the American College of Surgeons, said a clinical panel could raise the level of expertise in the field. "Why so much of the clinical research has fared so poorly is that these are terrible grants," she said. "Perhaps by establishing a mechanism that would be more critical of design, we would actually improve the science in that field."

"I still think that to some extent we are blind men trying to describe an elephant," Pollock said. "I would like more data."

"The data supporting this have been available

for a long time," Ehrenfeld said. "I'm not sure we want to start back that far. At some point we have to say that the data have been looked at and there have been large numbers of reports, all of which seem to come to some general conclusion."

"I will accept that," Pollock said. "I do want to make certain that as we move forward, if SEPs will be created, that we don't do something that damages the effective high-density study sections. There are some things about the status quo that are very good.

"I clearly discern a difference between human translational research and small clinical trials; they are different," Pollock said. "Human translational oncology research is adequately covered by the high-density study sections already in existence.

"For the small clinical trials, I would be very curious how the SEPs would improve that," Pollock said. "In my heart of hearts, I would like them to improve that, but the cynic in me says there probably aren't too many small trials that people are keeping in their desk drawer waiting for the SEPs to be created.

"The SEPs for small clinical trials would be outstanding; the SEP for large clinical trials would be outstanding," Pollock said. "But I don't want to see the translational research that is already adequately covered be clustered in there, because I think we would be potentially dismantling something that works well."

CSR Report: "Enough Studies Done," Time For Solutions

Following is the excerpted text of the draft report, "Review Of Clinical Research In The Center For Scientific Review."

Considerable concern about the vitality of the clinical research enterprise has existed in the investigator community for several years. These concerns include the adequacy of resource allocation, the dwindling young investigator base, the emerging importance of human translational research, the paucity of investigator-initiated small clinical trials, and the fairness of the Center for Scientific Review (CSR) review process.

There have been formal reports from the Institute of Medicine, and from two NIH panels of extramural experts, chaired by Gordon Williams (1994) and David Nathans (1997). The clinical research issues have been discussed within most Institutes, and have been treated with high priority in several. The Peer Review Oversight Group has identified clinical research as a focus and established a sub-committee to review the problem. For the last two years, the Director of NIH has responded formally in several forums to congressional concerns about clinical research. Specific interval responses to congressional concerns are requested this year.

Most of the above clinical research issues are matters of policy, program priorities, and budget allocations, and are only minimally related to CSR review processes. However, issues of review fairness, CSR infrastructure, and CSR flexibility are regularly noted by critique from internal and external constituencies. It is clear that although small, the CSR issues are not trivial and are surprisingly pervasive.

For the past several months, CSR has undertaken a study of its clinical research review processes. The Director, Ellie Ehrenfeld, retained Dr. Michael Simmons to assist her in this endeavor. Dr. Simmons chaired a committee of experienced and successful Scientific Review Administrators who provided insights into the present system and helped focus the development of new proposals. Drs. Ehrenfeld and Simmons met extensively with Institute Directors and staff and with a wide variety of extramural constituencies. The information, suggestions, perspectives, and recommendations of all of these groups were not only helpful, but directly determined the new processes which we propose to implement within CSR. We concluded early in our effort that enough studies have been done, and enough information has been collected by the several reports referenced above. We therefore focused our attention on defining solutions and implementation strategies.

It must be emphasized that substantial controversy exists within CSR, within the Institutes, and within extramural constituencies about what the problems really are. Reaching a satisfactory definition of clinical research has even been difficult. We have used the definition, quoted below, adopted by the NIH Director's Panel on Clinical Research, in their report to the Advisory Committee to the NIH Director in December 1997.

Clinical Research has three sub-types.

1. Patient-Oriented Research: Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes: Mechanisms of human disease, therapeutic interventions, clinical trials, development of new technologies.

2. Epidemiologic and Behavioral Studies

3. Outcomes Research and Health Services Research

We are most concerned about "translational research", which itself has different meanings to different constituencies. Although "translational research" may involve the new application of laboratory findings to a human disease problem (bench-to-bedside) or the laboratory testing of a hypothesis about a clinical observation (bedside-to-bench), some translational research may not fall under the above definition of clinical (patient-oriented) research at all. We have focused our concerns on the subset of translational research that includes the small clinical experiment which requires a bench-to-bedside-to-bench (or bedside-to-bench-to-bedside) series of actions on the part of an investigator. Most often, such research falls into the categories of mechanisms of human disease or therapeutic intervention.

Approximately 30% of all NIH funded research is "clinical." (If scored by the number of proposals funded, it is slightly less. If scored by the dollars expended, it is nearly 40%.) Although the majority of grants to the NIH are reviewed within CSR, most clinical research is reviewed within the Institutes. The amount of such review varies from Institute to Institute; in general, most such review is of proposals resulting from RFAs (or RFPs), or from multi-center cooperative groups or cooperative agreements.

The clinical research reviewed within CSR is principally investigator initiated translational research, or small single-center clinical experiments ("trials").

Implications of the Odd-Duck Problem

There has been the consistent assumption, within CSR and within the extramural constituencies, that productive and powerful review mechanisms can not be organized around narrow foci or themes, such as specific techniques, diseases, or model systems. The excellence of the present peer review system, derived largely of the above assumption, is self-evident. The careful combination within study sections of differentiated expertise, but with a broad biologic perspective, has served scientists and the science very well.

In reality, the composition and focus of study sections have varied widely. Some are "captive" of an individual institute. Some have evolved significantly since their initial charter. Some have changed very little, at a time when biology has evolved at a rapid pace. Some have welcomed and utilized as hoc reviewers extensively. Some have largely self-replicated themselves over time. Some study sections have been exclusively basic science. A few have had a high prevalence of clinical research.

Review within study sections could be organized down a biologic or clinical theme ("vertical organization") or with more diverse and eclectic expertise, focused around common biological processes ("horizontal organization"). For example, would review of the vision sciences be best served by a vision sciences study section? Or should these quite diverse proposals be distributed among photochemistry, developmental neurobiology, system neuroscience, integrative physiology or sensory science study sections?

In the past CSR has accommodated both organizational models.

Perhaps with new review criteria emphasizing impact, relevance, and creativity in addition to experimental approach, a more horizontal review composition is indicated. On the other hand, with the human organism, pathogenesis, and specific diseases progressively more complex, vertical organization around a theme (such as oncology, diabetes, cardiology) might implicitly define a broad and eclectic review mechanism.

The practical problem of the correct commonality or integrative theme around which one organizes review is a major challenge. Commonality in review of clinical trials could be achieved by establishing a review panel composed of experts in the design, conduct and evaluation of large, population-based clinical trials. The biologic expertise or disease expertise could be provided on an ad hoc basis. However, finding the commonality to review patient-oriented, translational research is a daunting problem. The diversity of expertise required (disease, organ system, biology, technology) is massive. Such a study section would likely have little integrative focus or glue.

The de facto response to the above daunting problem has been to distribute clinical research applications (and specifically translational research applications) over a large number of biologically focused study sections. The consequence has been that a significant number of such proposals have been reviewed in study sections with a low number and proportion (density) of clinical proposals.

Based on an analysis during 1994, 23 study sections review two-thirds of the clinical applications. The "density" of clinical applications in these study sections range from 30% to 100%. Nineteen study sections review no clinical applications. Forty-nine study sections review one-third of the clinical applications, with density ranging from 1 to 29%.

The Williams report illustrated that success rates in low-density study sections deviated substantially from high-density study sections. There may be a two-fold success advantage associated with a high density of clinical proposals within a study section.

Although the data from Williams focuses only on

the low-density disadvantage in clinical research, the argument is easily extended to other areas. Behavioral sciences, surgical sciences and biotechnology constituencies have all argued that distributing their proposals across multiple study sections (and invariably low-density ones) discriminates against them.

The precise validity of the data from the Williams report is still contentious, particularly within CSR. It does not seem useful to argue the precision of the data since by face value it should be evident that an adequate volume of proposals (experience) and appropriate reviewers (expertise) are basic components of fair review.

New Proposals for Review of Clinical Research Within CSR

A. The Low-Density Study Section Problem

Our analysis indicates two areas where review could be reorganized so as to cluster the clinical research proposals into a high-density study section: (1) cardiovascular science and (2) clinical oncology.

In each of these areas, CSR proposes to create a new special emphasis panel (SEP) for exclusive review of patient-oriented, translational research and small clinical trials. In those cases where an application would be moved from a low-density study section where it may have been reviewed before, or where the investigator has been reviewed previously, we will discuss the change with the applicant, encouraging input and self-referral. The details of implementation and piloting of these experimental SEPs have yet to be refined; we anticipate initiating them within the 1998 fiscal/calendar year.

Aggregating oncological science and cardiovascular science clinical review will address less than one-half of the low density problem. For those clinical research areas where the diversity of expertise required (disease, organ system, biology, technology) precludes sufficient commonality to form a cohesive cluster, we plan to test several possible approaches to address the odd duck problem.

1. We will test the model of an ombudsman for clinical research in a few low-density study sections. Such a clinical ombudsman would be asked to take a broad view of the study section's portfolio, and carefully review the clinical proposals for each round, focusing on impact, relevance and creativity. The ombudsman could be identified from within the existing membership or be recruited as an ad hoc reviewer. Different functions might develop among the several study sections.

2. A clinical research application that is reviewed in a low-density study section because of the presence of the required scientific expertise will be assigned to another, highly clinical study section for an opinion based upon the importance, potential impact and creativity of the application. This evaluation can be transmitted, along with the percentiled priority score, to the funding Institute(s).

3. A consistent practice of requesting outside opinions from clinicians in the field will be sought for the clinical research applications reviewed in low-density study sections.

4. A new SEP for "Human Investigations" will be tested for review of patient-oriented, translational research and small clinical trials applications that are collected from among proposals usually reviewed in several low-density study sections. The principal investigators will be informed of the option for review in the new SEP, and allowed to self-refer to either locus for review.

B. Large Clinical Trials, Health Services Research and Outcome Research

Within CSR, one study section has regularly reviewed research proposals using large populations focused on epidemiologic questions. A few other study sections have occasionally reviewed large clinical trials from investigator-initiated research applications. Most review of large clinical trials has occurred in the Institutes. These trials usually result from RFAs and RFPs. Cooperative agreements and cooperative groups also have a long history in several Institutes and are reviewed internally. Such research has been tightly linked to high priority program areas in the Institutes. This research has often begun in a rapidly emerging field of science where the relevance and impact are of great importance to an Institute. This tight connection between program and review in the early phases of new initiatives make obvious sense. Over time, having review remain intra-Institute is perhaps more problematic. The principle of ultimate separation of program and review has much to recommend it. Some Institutes have indicated a desire for an infrastructure and capability within CSR to accommodate such review.

Because few large population, descriptive clinical trials have been reviewed within CSR, there is presently little capability and limited capacity. We believe it is now an appropriate time to create a new review capability for population-based research within CSR. Many Institute based cooperative groups and cooperative agreements are aging. Several Institutes anticipate increasing investment in large clinical trials. If adequate capacity existed within CSR, we believe there would be a preference to move some review from the Institutes to CSR.

In addition, there has been much attention given

in the past few years to Health Services Research and Outcomes Research. It appears that activities in these areas will also increase across NIH. Presently, there is not adequate expertise within CSR, or adequate capacity, to offer review in these research areas. It is possible that investigators have been discouraged from applying to NIH in these research areas because of this deficit in CSR capacity and expertise.

We will establish a new SEP, the portfolio of which will include large (multi-center) clinical trials, outcomes research, and health services research. The regular members of the SEP will be experts in the design and execution of such trials. We anticipate having principally clinician reviewers who have a track record of conducting clinical trials. Appropriate experts in statistics and epidemiology may also be regular members. Because of the diversity of the clinical research which will exist within this SEP, we will rely heavily on ad hoc reviewers who will offer specific biologic and clinical expertise.

In Congress:

Anti-Tobacco Bill Gets Push From Gore, Democrats

Vice President Gore and Democratic lawmakers last week rallied in support of a bill that represents one of the toughest antismoking measures pending in Congress.

The bill, written by the Senate Democratic Task Force on Tobacco, headed by Sen. Kent Conrad (D-ND), would raise the price of cigarettes by $1.50 per pack over three years, a faster increase than the 10-year period envisioned in President Clinton's budget proposal.

The Healthy Kids Act (S. 1638) also would grant FDA full authority over tobacco products, install "look-back" penalties on manufacturers, fund anti-tobacco research, and enforce tougher retailer compliance measures.

Twenty-one percent of the revenues would be invested in health research at NIH. Revenues from the bill could be as high as $82 billion over five years, Conrad said.

"President Clinton strongly supports this bill and would gladly sign this bill if Congress puts it on his desk," Gore said at a Feb. 11 rally of Democratic lawmakers and public health advocates.

Gore's praise of the bill, without specifically endorsing it, was seen as a move by the Administration to generate momentum on the tobacco issue and make a distinction between "comprehensive" legislation and more modest, focused bills being introduced by some Republicans.

"The President and I simply cannot get behind a watered-down, piecemeal bill," Gore said.

The Democratic bill would ban smoking in public facilities other than bars, casinos, nightclubs, and other adult-only establishments; force the tobacco industry to make public documents on health research, nicotine manipulation, and marketing to children; and create provisions that would contribute to international tobacco control efforts.

Other members of Congress have criticized the bill as being overly partisan and destined to fail in Congress.

"This is an issue that cries out for bipartisan leadership, and, frankly, a bill written solely by the Democratic Caucus is not going to get the job done," said Sen. John Chafee (R-RI).

Chafee, co-chair of the Congressional Task Force on Health Care Quality and a member of the Senate GOP Task Force on Tobacco, is crafting a bipartisan tobacco bill with Sen. Tom Harkin (D-IA).

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NCI research supports the "comprehensive" approach to tobacco control, an Institute official said at a Senate hearing last week.

"Although we know that a price increase is one of the most effective single interventions to reduce teen smoking, it should be augmented with other kinds of interventions, such as educational programs, mass media programs, and restrictions on tobacco advertising and sales to minors," Marc Manley, acting associate director of the behavioral research program in the Division of Cancer Control and Population Sciences, said to the Senate Committee on Labor and Human Resources at a Feb. 10 hearing.

"The President's recommendations to Congress about the essential elements of a tobacco control program are certainly consistent with the scientific literature," Manley said.

"An innovative tobacco control research program is essential to guide new policies, regulations, and programs that are being supported by public and private funds," Manley said.

Research is needed to understand the initiation of tobacco use and nicotine addiction, and racial, cultural, and gender influences in youth tobacco use, Manley said. Clinical studies are needed of treatment regimens using combinations of devices, drugs, and behavioral interventions to help people quit smoking.

New assessment tools need to be developed to measure the success of community intervention programs, he said. To advance research in tobacco-related cancers, NCI's clinical trials cooperative group program requires additional resources so that all eligible cancer patients could enroll in clinical trials for cancer treatment, prevention, detection, and diagnosis, Manley said.

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A bill that would prohibit human cloning through somatic cell nuclear transfer technology was stopped from reaching the Senate floor by a vote of 54-42 last week.

The Human Cloning Prohibition Act (S. 1601), introduced by Senate Majority Leader Trent Lott, had 14 co-sponsors including Sen. Bill Frist (R-TN), the Senate's only physician.

Opponents said the bill language was too vague and would inhibit medical research.

Letter to the Editors:

Disheartening To Think About Potential Loss Of ET2

To the Editors:

As a physician-scientist who has served on the Experimental Therapeutics 2 study section for the last six years (and has agreed to one more four-year term), I have a number of insights regarding the proposed modifications to the review of patient-oriented research (**The Cancer Letter**, Feb. 13).

Despite the many outbursts by the American Society for Clinical Oncology, articles in the Journal of the American Medical Association, etc., ET2 has never considered patient-oriented research to be less desirable or meritorious than laboratory based research. There are two kinds of patient-oriented research that ET2 typically has reviewed. The first kind are laboratory/clinical studies specifically designed to utilize the lab to guide or assess some set of studies and correlate them with the actual treatment of patients. These studies have always faired extremely well in our study section since they are in general written by physician-scientists who know how to conduct hypothesis-driven research in a meaningful fashion. Some of the highest scores that we have ever given were given to such applications.

Unfortunately, the vast majority of patient-oriented research that comes to ET2 represent either clinical trials with a "drug du jour" or a clinical trial with an incredibly poorly designed non-hypothesis-driven laboratory correlate. These applications are poorly received, since, even if patients are recruited to these trials, it is unlikely that meaningful data will result. These are the applications for which certain organizations continually cry foul with regard to the way they are reviewed. In point of fact, these are extremely limited studies.

My concern with the potential dissolution of ET2 is based on several considerations:

—If a clinical study section is going to review all patient-oriented research, those applications which are true hypothesis-driven, well-designed proposals will fare well as long as they are reviewed by a group of clinical investigators and scientists who understand the issues at hand. Many clinicians have not been trained to review applications which include substantial laboratory correlative studies. It is easy to say that tumor samples will be sent in for certain assays, but if you do not know how to do the assays, deal with contaminating tissue, understand the problems associated with these studies, etc., clinical trials based on laboratory correlates which will never be successfully conducted may well be funded.

—Clinical trials evaluating a drug du jour will never fare well in comparison to these other studies. If the goal of the NCI is to fund such clinical investigations using the R01 mechanism, then it would be appropriate to set aside money specifically for non-laboratory driven clinical trials.

—If a new study section reviews patient-oriented research, who will then review translational studies? Basic science could be reviewed in other sections (perhaps ET1), but true translational science requires a study section composed of both clinical and laboratory investigators, with the clinical investigators being physician-scientists. Termination of ET2 will require that a new home be found for the review of such applications. There is no such study section that I am aware of which is capable of handling these applications.

As a physician-scientist whose entire clinical program is based on the laboratory and who conducts basic studies, translational studies, and clinical investigations, it is disheartening to think what the loss of ET2 will mean.

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