Report of the Education Breakout Session
CTSA Consortium Oversight Committee Meeting
January 15, 2008
Attachment A

The Education Breakout Session Group discussed a number of issues related to Clinical and Translational Research Training on January 15, 2008. The results were presented to the full CTSA Consortium Oversight Committee on January 16, and further discussion took place at that time. The summary below reflects both sets of discussions. They will be shared with the Education/Career Development Steering Committee at its next meeting.

1. Descriptions of Programs Initiated at CTSA Sites.

a) Degree-granting Master's programs have been established at all sites represented. Some programs have multiple tracks (up to 5 reported) within their programs and some require that trainees have at least two different mentors.

b) There is variability in PhD programs at different sites, and not all sites offer PhD degrees. Most PhD degrees are non-departmental, reflecting the success of the CTSAs in eliminating departmental barriers for the training mission. In some institutions, a 4-year PhD, separate from the standard basic science PhD, is offered, whereas in other institutions, there is no time limit so as to avoid the perception of there being two tiers (or classes) of PhDs. In one institution, trainees enter the Master's program first and have the option of applying for entry into the University's single PhD program after 2-3 years. This avoids the appearance of having two tiers of PhDs. Differing views were expressed about the suitability of Clinical and Translational Science PhDs as part of institutional MSTP MD-PhD programs, with one PI expressing reservations about trainees being able to perform patient-oriented research early in their pre-clinical years and others less concerned about this issue.

c) Emphasis on writing NIH grant proposals early in the training program has correlated with success in obtaining such grants in some institutions.

d) Several institutions offer "Certificate" programs for basic science PhD students who wish to have an introduction to clinical and translational science. Although it is too early to asses the impact of these programs, they have undoubtedly enhanced awareness of clinical and translational science among the trainees.

e) A few institutions have developed curricula to introduce undergraduate students to clinical and translational science. The outcomes from these programs will be very informative in judging the effectiveness of this strategy.

f) The NIH Clinical Center has had extensive experience training people in clinical and translational science, with more than 13,000 people completing their curriculum. At one point, the Clinical Center explored the possibility of obtaining ACGME approval for a new subspecialty in Clinical and Translational Research

but the Clinical Center ultimately decided not to pursue this path for a number of reasons.

2. Transition from K-12 Program to Other Awards

a) The policies of Institutes to cap the maximum duration of mentored training (K12 + K08 or K12 + K23) to 6 years was again identified as a serious impediment to the success of the training component of the CTSA program. The data demonstrating that first time MD R01 recipients average 44 years of age indicates that 6 years of mentored research time is highly unlikely to be adequate for all but the very few trainees who enter K12 programs with extensive research experience. It also was pointed out that there is an inconsistency in expectations between MD and PhD investigators since PhDs have ~5-6 years of mentored doctoral research training followed by 4-5 years of mentored postdoctoral research training, for a total of up to 11 years of mentored research experience. Thus, the playing field is far from even for MDs and PhDs applying for first-time R01s. It appears that at least a few Institutes are reconsidering their policies and may be agreeable to 8 years of training for individuals seeking 5 years of a K08 or K23 grant after 3 years of a K12 grant.
It is well-established that research productivity for early phase clinical and translational scientists tends to take a variably long period of time to nucleate, followed by an inflection point and a much higher rate of productivity. There is a serious danger that not providing the last 1-2 years of support needed to get beyond the inflection point could disproportionately result in failure of trainees to ever achieve independence, and thus imperil the success of the CTSA training component. Anecdotal evidence abounds of trainees choosing to drop out of academic careers after many years of training because of the lack of funds to allow them additional time to demonstrate their research potential, and NCRR has identified this period as one of great vulnerability. Thus, there remains strong for NIH developing a uniform policy allowing 3 year K12 grants followed by 5 year K08 or K23 grants.

b) Concern was expressed about whether the review criteria for K08 and K23 awards are inadvertently discouraging and unfairly penalizing translational scientists. Anecdotal evidence indicates the K08 study sections may be inappropriately critical of human studies, even when part of an integrated basic science program, and vice versa, K23 study sections may be inappropriately critical of basic science studies, even when part of an integrated program that includes human studies. The PIs recommended a full review of the K08 and K23 review criteria, the expertise of the study sections, and the charges to the study sections. In particular, it was emphasized that study sections should be required to request ad-hoc reviewers when they lack the expertise to judge the merits of a proposal.

c) The group reviewed the K99/R00 program for Clinical and Translational Scientists. Although the 2007 RFA is an improvement over the 2006 RFA, serious concerns remain about its attractiveness for physician scientists. First, the eligibility criteria are ambiguous since there is no explicit statement about how fellowship research training is counted with regard to the 5 year research

limit, and this needs to be reviewed on a case by case basis with an NIH official. MD-PhD graduates are eligible with up to 5 years of research experience after completing both their MD and PhD degrees. Thus, they (like PhD applicants) are likely to have a total of 9-10 years of mentored research experience in total. In sharp contrast, MD only investigators who did not do research in medical school lose their eligibility if they have more than a total of 5 years of mentored research experience. This fundamental inequity needs to be addressed. A total of 3 years of a K12 and 2 years of a mentored K99 is not likely to be sufficient to reach independence for the vast majority of trainees performing clinical and translational research, especially for "late bloomers." The exclusion based on having "an independent research faculty or tenure-track faculty position or its equivalent" would not necessarily exclude an MD who holds an Instructor or Assistant Professor position based on their clinical skills if they meet the criteria for not having attained research independence. These criteria are defined for PhDs and MD applicants in the RFA, but with the very strong recommendation that applicants contact a Program Director at the relevant NIH Institute to establish eligibility on a case by case basis. There is also great uncertainty about the mechanics of the transition to the R00 portion of the grant and how to mentor trainees through a period filled with uncertainty that is likely to be very anxiety provoking and thus may detract from productivity. Thus, while the K99/R00 may be very desirable for a small number of clinical and translational investigators, the 2007 RFA does not address most of the key concerns of the PIs and trainees. Dr. David Wilde told the group that fewer than 5% of the K99/R00 awards last year went to MD investigators and slightly more than 5% went to MD-PhD investigators. We do not, however, have information on the success rates, that is, the percentage of applicants in each group who were successful in obtaining the grant. One member of the group who participated in the review process expressed concern that the competition for the awards was fierce and that many high-quality applications were not funded.

3. Retaining Physician Scientists in Research Careers

The difficulties in retaining physician scientists in research careers were discussed at length. Data indicate that the attrition rate for women is much greater than that for men, suggesting that the stress of family responsibilities falls disproportionately on female trainees and junior faculty. NCRR is hosting a meeting in early March to address the issue of enhancing the retention of women in academic medical careers. Dr. Wilde emphasized the importance of having supportive policies from the institution, the granting agency, and the mentor since it is crucial that all three convey the same message. NIH grants have a provision to allow a 3 month maternity leave. However, there is no specific place on an R01 grant proposal to explain how life events or family responsibilities may have had an impact on research productivity.

One of the PIs expressed serious concern about the unrealistic expectations he has encountered among junior clinical researchers who are negotiating their first appointments. Specifically, unlike basic scientists, they do not have a clear conception of what is expected of them with regard to research productivity and grant support. This led to a discussion as to whether there would be value in developing a "CTSA handbook" for junior investigators, outlining goals and expectations, and/or a "CTSA Model Appointments, Promotion, and Tenure Policy" for clinical and translational scientists. The

latter would define rigorous, but fair, criteria for judging the achievements of clinical and translational scientists, and could serve as a template for adoption at academic institutions. Concern was expressed that the latter might be misconstrued as indicating that clinical and translational scientists were not subject to the same criteria of excellence as other faculty members, in which case it could have a negative impact on institutional respect for clinical and translational scientists. It may still be desirable, however, to define general criteria that are equal in rigor to the institutional policies for other faculty while having the criteria reflect the unique features of clinical and translational science.

4. Venue of K12 Annual Meeting

The venue of the annual K12 meeting was discussed in some detail. Currently, the meeting is being held in Washington in conjunction with the annual meeting of the Association of Clinical Research Professionals, which has been very helpful in administering the meeting, although with quite high registration fees. Dr. Coller praised both the process by which the agenda of the meeting has been developed and the agenda itself, which is targeted to the most important issues facing K12 trainees. The program committee has reached out for input from all of the CTSAs as well as K12 trainee representatives from each CTSA. One possible alternative venue would be the ASCI/AAP meeting since it brings together many of the leaders of academic clinical investigation and the scientific presentations are, in general, of the highest quality. It is not clear, however, as to whether these organizations would welcome having the K12 meeting connected to their meeting. Moreover, one PI expressed very serious concern about meeting with the ASCI/AAP because their meeting contains very little T2 translational research and trainees who focus in this area may feel uncomfortable at the meeting. Moving the meeting from Washington to Chicago, would also have a negative impact on NCRR's travel budget for NIH personnel. A show of hands found that only a minority of the PIs favored connecting with the ASCI/AAP meeting, but it was agreed that Dr. Coller should contact Dr. Charles Sawyers, President of the ASCI to assess the organization's interest and whether they would try to accommodate some of the concerns that had been expressed.

5) Availability of Cross-CTSA Research Electives

Electives among cooperating institutions within the CTSA were briefly discussed. Since trainees may wish to spend time on electives at sites other than their own home institution, it was suggested by one PI that the CTSAs discuss whether they would be willing to offer preferential access to electives in their centers to trainees from other CTSA sites.

6) Web-Based Educational Tools for Clinical and Translational Research

Optimal use of web-based learning tools was discussed at length. It was agreed that there are several different reasons to consider web-based learning techniques. The first is when no institution has individuals with both the full range of scientific expertise and outstanding teaching skills required for the subject matter. One example was the proposed Curriculum in Computational Literacy for Clinical and Translational Scientists. A second situation is when core case-based materials can be provided to all sites, to be

complemented and supplemented with discussions and additional materials at each site. Clinical trial design studies, preparing a grant proposal, and bioethical issues lend themselves well to this format. A third motive for web-based learning is when the subject requires faculty from federal agencies, such as the FDA, CDC, NLM, and OHRP. It is crucial for translational scientists to have a sense of both the mission of the FDA and the processes it uses to support that mission. It is equally important to have a sense of the regulatory culture and the challenges the FDA faces in balancing the protection of individual participants and obtaining the information required to decide whether an intervention is safe and effective enough to be approved for use in the general population.

With so many web-based materials being produced, it is important to know both what is available and what is the quality of the material. Thus, it would be very valuable if the CTSA Education/Career Development Committee took on the responsibility of sharing the experiences of the members regarding these resources and rating them for their value as part of clinical and translational research training. One PI pointed out that with more medical students and trainees studying abroad, web-based materials have the ability to reach individuals anywhere in the world where there is internet access. Another PI indicated that long distance learning tools using live video-casting can provide a valuable tool to bring entire courses to sites that do not have programs. In addition, live video casting provides the potential for a CTSA seminar series integrating the core teaching strengths from multiple sites; this might be a worthwhile experiment. The NIH and Duke University have successfully used live video cast teaching in this way.

7. Integration of Consortium Oversight Committee Views with Those of the Education/Career Development Steering Committee

The PIs reviewed the upcoming meetings of the Education/Career Development Steering Committee and the workshop to develop a national curriculum for clinical and translational investigators. The PIs were reassured by reading that the goals of the latter meeting are to define the knowledge, skills, attributes, and competencies required for a successful career in clinical and translational science, rather than the creation of a formal national curriculum and/or syllabus. It was agreed that different institutions may choose to teach the material in different ways and that there is benefit in having a variety of alternative approaches from which all CTSAs can learn. Moreover, there already are excellent basic sources, such as John Gallin's book, which can serve as core curriculum equivalents. The creation of textbooks is probably best left to the private sector where interested and motivated educators can obtain the resources needed for publication and marketing, and competition can drive quality and timely updating.

8. Team Building and Team Leadership in Clinical and Translational Research

The discussion of the skills needed to succeed in clinical and translational research led to a discussion of the importance of trainees developing skills in team building and team leadership, which are not commonly a part of traditional training programs. Dr. Zerhouni emphasized the importance of identifying and nurturing the precious few with remarkable talents ("235 U") and grooming them for leadership positions. One of the CTSAs has arranged for a week-long elective for trainees at a

large pharmaceutical company, with a focus on team building and timeline management, two strengths of industrial structures.

9. International Clinical and Translational Research Training Initiative

Clinical and translational science educational initiatives are underway outside of the U.S., inspired at least in part, perhaps, by the NIH CTSA initiative. Some CTSA PIs are advising governments and foundations around the world on how best to structure such initiatives, including one's sponsored by the Wellcome Trust, Israel, and Singapore. It may be valuable to have periodic reports about the different approaches that are being taken by these foundations and governments in the hopes that some novel ideas may emerge that are appropriate for implementation by the CTSAs in the U.S. The NIH Fogarty International Center (Dr. Roger Glass Director) has some international clinical and translational training initiatives and should be contacted to facilitate partnerships and avoid unnecessary duplication of effort.

10. NIH and Professional Society Initiatives in Clinical and Translational Research Training

Some NIH institutes and professional societies are beginning to sponsor intensive experiences in clinical and translational science training. For example, NIGMS sponsors short courses in pharmacology and the American Society of Hematology has a yearly one-week immersion course for trainees who want to work on the design of a patient-oriented research proposal. These initiatives may be of interest to K12 trainees, and educators in CTSAs may benefit from the experiences gained by these programs.

11. Impact of Board Certification on Clinical and Translational Research Training

One PI raised the issue of the impact of board certification on the training of junior clinical and translational physician scientists. In particular, it may be timely to review the ABIM research track with regard to its merits and drawbacks for physician scientists contemplating a career in clinical and translational science.

12. Identification of Careers Beyond Training

There was a brief discussion of the types of careers the K12 program is training people for, and whether opportunities for gainful employment actually exist in industry and academia. There was a consensus that there are positions available for successful translational investigators and that it was desirable for some trainees to have careers in industry for the success of the broader goals of the program.

13. Developing a Cultural Identity for Clinical and Translational Science

One PI emphasized the need to create an entirely new discipline of clinical and translational science and another emphasized that this ultimately required the creation of a new cultural identity. Organ-based subspecialties have been able to maintain such identities even though individuals within the discipline may be spread across a variety of different sub-subspecialties and across the continuum of basic research to clinical care. It is intrinsically more difficult for clinical and translational science to achieve this same

level of cultural identity because it cuts across all of the other organ-based disciplines. As a result, individuals must be able to develop both an organ-based identity and a clinical and translational science identity. The K12 training program and annual meeting have the potential to begin to create such a cultural identity, but it will likely require an established national meeting attended by many of the senior members of the discipline, a national society, and a prestigious journal, to make significant progress in establishing a cultural identity for the new discipline. Alternatively, having formal training in clinical research as a part of subspecialty training that would result in certification in a traditional subspecialty with accreditation in clinical and translational research would achieve the objective for a career path in a traditional subspecialty with appropriate credentials and cultural identify as a clinical investigator.