

**Informatics Session  
CTSA Consortium Oversight Committee Meeting  
January 15, 2008  
Attachment B**

**Attendees in Rockville:** Gordon Bernard; Frank Arnett; Lars Bergland; Julian Solway; Robert Califf; Brian Athey; Elaine Collier; Greg Farber; Leslie Derr; Jean Stanford; Anthony Hayward; Jody Sachs

**Virtual Attendees via Adobe Connect:** Bill Hersh; Jonathan Silverstein; Perry Miller; Elmer Bernstam

Dr. Bill Hersh, Chair of the Informatics Steering Committee, updated the assembled CTSA PIs via Adobe Connect on the activities of the Steering Committee. The Informatics Steering Committee recently established a smaller Operations Committee to provide leadership for the Informatics Committee and oversight for the multiple working groups within the Steering Committee. Bill and other members of the Operations committee were present at the break out session through Adobe Connect and Brian Athey, the co-Chair of the CTSA Informatics Steering Committee, was present at the meeting. The Informatics Operations Committee members expressed the wish to have several liaisons from the CTSA PI Steering Committee to the Informatics Committee to provide a mechanism to assure the activities of the Informatics Consortium were consistent with the perceived needs of the CTSA PI Consortium. The PIs expressed approval and enthusiasm for the establishment of the Operations Committee and also for the designation of liaisons from the PI committee to the Informatics Committee.

A discussion of the current Interest and Project Groups followed. The Education Project Group is focused on integrating informatics into the curriculum for clinical and translational training programs. In addition to the focus on what clinical and translational researchers need to know about informatics, they will also address what informatics researchers and professionals need to know about clinical and translational research to be effective in advancing these areas of science. The PIs strongly supported the integration of informatics into the competencies and curricula for masters and doctoral students in clinical and translational science.

The Inventory and Resources Project Group is developing an inventory of informatics resources at CTSA's to assist informatics staff in finding available tools. This led to a discussion of the tools that PIs would like to have available at their sites. These ranged from communication tools to registries of individuals interested in participating in clinical studies. The PIs encouraged the group to foster sharing of tools and not re-development of already existing tools at other sites. Vanderbilt has many tools they are willing to share and Chicago indicated they would be interested in possible adoption of tools for particular tasks.

The Human Studies Metadata Repository Project Group is focused on developing agreed on standards for a set of metadata about clinical research studies at CTSA's. The initial focus is on those fields needed for clinical trial registration as recently mandated by FDA Amendments Act. The group is currently developing use cases to

drive the focus of the group. There is overlap with a task force in the CTSA Administrators group and also the CTSA Regulatory group.

The CTSA Informatics Steering Committee is drafting a white paper for publication in a journal that discusses the synergies of informatics, information technology, and computer science. The PIs expressed enthusiasm for this and encouraged the development of additional white papers on other topics.

A general discussion of the priorities of the needs of the CTSA related to informatics covered many areas and the PIs encouraged sharing of information and tools and further discussion of the highest priorities. This will be pursued by the Operations Committee through the new CTSA PI liaisons. Gordon Bernard of Vanderbilt University and Julian Solway of University of Chicago agreed to be the CTSA PI liaisons to the CTSA Informatics Steering Committee.

Attachment:

***Draft CTSA National Informatics Steering Committee Operational Plan***

CTSA Informatics Operations Committee:

William Hersh, MD - Chair, Oregon Health & Science University  
Brian Athey, PhD - Co-Chair, University of Michigan  
Mike Becich, MD PhD - University of Pittsburgh  
Elmer Bernstam, MD - University of Texas Health Sciences  
Dan Masys, MD - Vanderbilt University  
Perry Miller, MD, PhD - Yale University  
Jonathan Silverstein, MD - University of Chicago  
Elaine Collier, MD - National Center for Research Resources  
Milt Corn, MD - National Library of Medicine  
Greg Farber, PhD - National Center for Research Resources

The goal of the CTSA National Informatics Steering Committee is to promote biomedical informatics approaches and support within, among, and beyond CTSA centers. The voting members of the Steering Committee consist of one representative from each funded CTSA center, along with designated representatives from various NIH Institutes, Centers, and other Federal agencies. However, any individual from any biomedical informatics program within a funded center as well as others from NIH or other agencies can participate. The committee is led by a chair and co-chair, and is governed by an Operations Committee consisting of seven members from funded centers and three members from NIH.

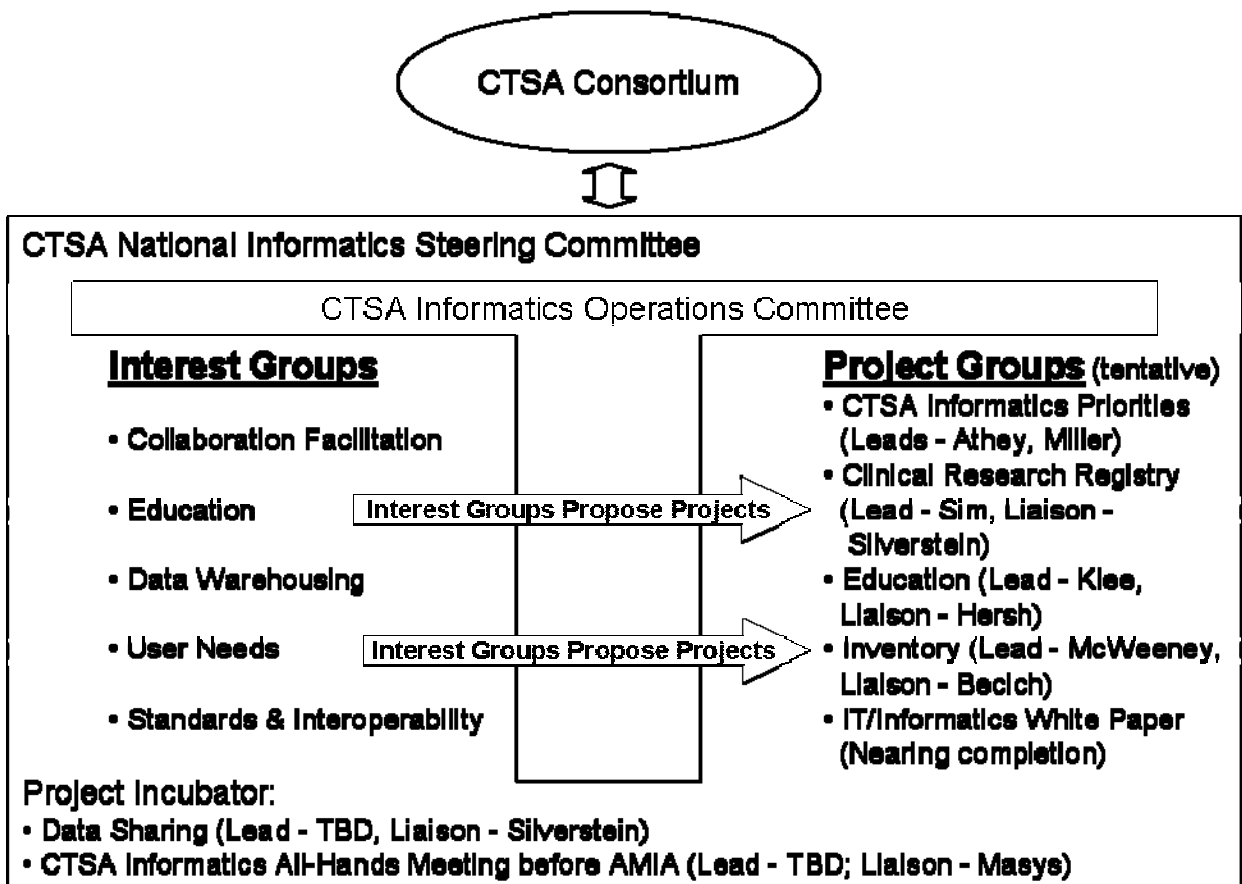
As with most CTSA activities, the activities of the committee have progressed by trial and error. The current approach described in this document builds upon the experience gained from earlier efforts. From the beginning, the Steering Committee tried to draw its priorities from its membership, with the goal of focusing on biomedical informatics activities that would support areas of common interest and promote the value that informatics is expected to bring to the clinical and translational research enterprise both locally at member institutions and nationally.

Our initial efforts consisted of developing working groups to address specific issues. The process was challenged by working groups having difficulty developing an integrated set of objectives, strategies, plans, and deliverables. In addition, some of the groups could not reach consensus and/or the timely achievement of goals due to competing member opinions. Furthermore, working group members had difficulty prioritizing time for local day-to-day activities versus this nationally focused collaborative activity. By the end of 2007, it became apparent that the National Informatics Steering Committee needed to have governance by an Operations Committee that would set strategic direction, prioritize activities, and insure timely deliverables.

At a strategic planning meeting in Bethesda on January 9, 2008, the Operations Committee developed a plan of operational activities to insure the maximal impact that informatics can have on the goals of the CTSA. We believe that this plan will enable us to serve as a forum for general informatics activities in the CTSA program but also identify explicit areas where accomplishment is most highly prioritized. We want the CTSA National Informatics Steering Committee to serve as a venue for all informatics ideas and goals for the CTSA Consortium, where informaticians from all centers can come together to brainstorm, collaborate, and develop vision for the best use of informatics in clinical and translational research. Yet we also want to set as highest priority for the group a small number of activities that will provide the most value to the CTSA Consortium. We also want the Operations Committee to view itself as the liaison between the informatics groups and the CTSA Consortium Oversight Committee. We hope one or two PIs will emerge as liaisons from the Consortium Oversight Committee.

To this end, we are recasting the working groups into two types of groups. One type will be interest groups, which will be broad-based groups that bring together interested members of the CTSA Consortium to focus on informatics issues of concern across centers. These groups will be supported through call-in lines for meetings, space on the wiki, and vehicles to publicize their work. From these interest groups will emerge more focused project groups, whose activities will be more focused on specific activities and deliverables. Some of the projects of the project groups will be time-limited, while others will be phased. However structured, these projects will be vetted and prioritized by the Operations Committee, based on a voting process (to be determined) by the voting members of the National Informatics Steering Committee that is transparent yet enables work to progress in a timely manner.

Each project will have expected deliverables, dates for completion, and documentation on the CTSA wiki. A member of the Operations Committee will serve as a liaison to the project group. Projects may be nominated by an interest group or directly by the Operations Committee. The Operations Committee, however, will appoint the project leader; approve the goals, deliverables, and timeline; and monitor its progress. The Operations Committee will also maintain a short list of potential projects that will be viewed as an “incubator” for future projects. The figure below diagrams our new structure.



The Operations Committee will meet monthly by conference call for their work in addition to the currently scheduled Informatics Directors' call, which will include the informatics directors and project group leads. The Operations Committee call will take place on the fourth Friday of the month at noon Eastern time. The Informatics Directors' call will continue to take place on the first Friday at 1 PM Eastern time. The Operations Committee will meet face-to face twice per year, at least once in the Washington, DC area.