**Data Sharing and Intellectual Capital Working Group Teleconference, September 30th, 2004, 2:00 pm EDT**

**Data Sharing and Intellectual Capital Working Group Teleconference**

| **September 30, 2004** | 2:00 pm EDT |
|---|---|
| **Attendees:** | City of Hope: Joyce Niland<br>Cold Spring Harbor Laboratory: Brian Gilman<br>Fred Hutchinson: Bob Robbins<br>Jackson Laboratory: Carol Bult<br>Oregon Health and Science University: Ed Quick<br>Thomas Jefferson University—Kimmel: Absent<br>University of Arizona: Lana O'Brien<br>University of Iowa: Terry Braun<br>University of Michigan: Elaine Brock<br>University of Minnesota: Absent<br>UNC – Lineberger: Absent<br>University of Pittsburgh: Rebecca Crowley; Linda Schmadt<br>Washington University—Siteman: Mark Watson; Misha Thomas<br>U Penn-Abramson: Howard Bilofsky<br>Fox Chase: Pat Harsche-Weeks, Amin Chisti<br>Dartmouth: Louise Rosenbaum<br>Patient Advocate: Deborah Collyar<br>NCI: Wendy Patterson, Leslie Derr<br>BAH: Phan Winter |
| **Introduction** | Wendy Patterson opened the meeting, reviewed the agenda, and introduced new DSIC participants:<br>• Elaine Brock from University of Michigan<br>• Rebecca Crowley from University of Pittsburgh<br>• Lana O'Brien from University of Arizona<br>• Deborah Collyar – PAIR (Patient Advocates In Research) |

| | |
|---|---|
| | Deborah Collyar briefly described her background to the WG. A cancer survivor, Deborah provides a patient perspective on research for the NCI SPORE program. She is especially interested in IRB and HIPAA issues.<br><br>The group did not offer comments on the notes from the 9/2/04 teleconference. Members were encouraged to e-mail any corrections to Phan within the next two days. Phan will post the notes as final to the caBIG forum website within the next week. |
| **Report from Liaisons** | Architecture: Bob Robbins (Fred Hutchinson)<br><br>The Architecture Workspace is collaborating with NCICB on WS activities such as caDSR and caBIO, and needs recommendations on IRB compliance and patient consent issues. The faster the DSIC WG can make these recommendations to the Architecture WS, the better.<br><br>Strategic Planning: Joyce Niland (City of Hope)<br><br>A face-to-face meeting tentatively scheduled for late October has been postponed to some time in November. The last teleconference focused on planning for this meeting.<br><br>Written reports submitted for the following groups before the teleconference and will be posted on-line as an appendix to these notes:<br><br>• Integrative Cancer Research: Terry Braun (University of Iowa – Holden)<br>• Clinical Trials: Don Connelly (Minnessota)<br>• Tissue Banks and Pathology Tools Workspace: Mark Watson (Washington University - Siteman) |
| **DSIC WG White Paper Topics** | Wendy raised the white paper topics as a follow-up to the last teleconference. The purpose of drafting white papers is to lay the foundation for guidelines and recommendations for best practices that can be offered to the caBIG community. To accomplish this goal, the DSIC WG wards need a well thought-out process for development of the white papers. Wendy reviewed the following topics listed in the agenda and asked for additional suggestions:<br><br>1. The impact of IRBs and Patient Consent, HIPAA privacy and security rules on the aggregation, storage, and |

analysis of specimens and data from clinical trials.

2. The means of protecting intellectual capital while allowing for the exchange of scientific information among cancer researchers
3. The role of intellectual property in the caBIG project
4. Software specification recommendations for inclusion in systems providing federated data to the community.

Amin Chisti suggested that the group consider the issue of leveraging software commercialization opportunities. Specifically, what should be the policy recommendation on how to address business opportunities for commercialization of caBIG software? What are best practices for how to respond to private sector interest? How should ca BIG capture software commercialization opportunities?

The group raised questions about the differences between topics 2 and 3. What does it mean to protect? Is there a difference between asserting copyrights and retaining commercial benefits? What is the meaning of intellectual capital as opposed to intellectual property? Does topic 2 address the problems of the knowledge commons? The group thought that topic 3 could be broken down into issues relating software, data, and biospecimens. After some discussion, the group concluded that topic 1 concerned regulatory issues intended to protect patients, whereas topics 2 and 3 address matters pertaining to investigator and institutional interests.

Wendy pointed out that whereas intellectual property refers to proprietary rights such as patents and copyrights, the concept of intellectual capital is designed to capture something broader. It is aimed at the problem that many researchers face when generating data -- that it is better to restrict access to data than to share it widely. The intellectual capital protection topic should address how researchers who share immediately protect their interests and how they get credit for sharing.

Pat noted that copyrights are often perceived as being owned by the author, but that ownership may actually vary depending on whether the data is generated from federal grant awards or other sources of funding. She also wondered if it might be better to put certain intellectual capital in the hand of commercial entities, which provides incentives to move things forward.

Pat recommended that the white papers developed by the

DSIC WG propose a core of principles and a range of solutions or best practices. The group agreed with this suggestion.

Elaine Brock thought it would be logical to inventory the existing information on the issues mentioned above, such as the question of credits for intellectual capital. By exploring and building ethical norms and getting early buy-in from the community, it may be possible to develop recommendations without touching intellectual property and ownership issues. She also pointed out that sometimes universities prefer to grant exclusivity because it results in a better product in terms of maintenance and support. She also thought the group should consider standards for open source in shared projects.

The group wondered whether the team handling topic 1 should consider the FDA's compliance rule contained in 21 CFR Part 11. Bob Robbins explained that this regulation deals with authentication of electronic records and signatures, which is distinct from topic 1. The group was concerned that topic 1 deals not only with patient protection issues but also with the regulation of data and information flow in caBIG, which has implications for software design. Although group members agreed that topic 1 and 4 are closely related, with group 4 functioning as an interface between topic 1 (and 2/3) to the Architecture Workspace. They ultimately concluded that teams focusing on these topics should work closely together.

Bob voiced concern that the DSIC WG's responsibility for developing definitive caBIG papers will take a tremendous amount of time and will not meet the immediate needs of the Architecture WS. He mentioned a meeting that he will attend in late October where each participant presents a position paper. He expects lively discourse around these papers that could bring meaningful results. He suggested that the DSIC WG adopt this format as a process to assist in the development of white papers.

Leslie suggested that these details be addressed by the teams handling these topics and that the WG proceed to form teams to work on these topics.

**Teams for development of topics**

DSIC members volunteered for the topics listed above. Based on the discussions noted above, the group consolidated topics 2 and 3. The teams were formed as follows:

| DSIC WG Teams | Members |
|---|---|
| Regulatory team – oriented toward protection of patient rights:<br>• The impact of IRB/Patient Consent/HIPAA privacy and security rules on the aggregation, storage, and analysis of specimens and data from clinical trials. | Joyce Niland<br>Howard Bilofsky<br>Elaine Brock<br>Deborah Collyar<br>Don Connelly<br>Joyce Niland<br>Ed Quick<br>Bob Robbins<br>Mark Watson |
| Proprietary team – focused on individual researcher and institutional interests:<br>▪ The means of protecting intellectual capital while allowing for the exchange of scientific information among cancer researchers; the role of intellectual property in the caBIG project. Issues can be examined in three areas: data, software, and biospecimens | Carol Bult<br>Don Cecchi<br>Amin Chisti<br>Brian Gilman (?)<br>Pat Harsche-Weeks<br>Mark Watson<br>Vincent Yau |
| Leverage team – geared toward public-private partnerships to achieve caBIG goals:<br>▪ Leveraging software commercialization opportunities | Amin Chisti<br>Deborah Collyar |
| Specifications team – interface from DSIC WG to Architecture Work Space<br>▪ Recommendations for software (and other?) specifications to be included in systems providing federated data to the community | Amin Chisti<br>Rebecca Crowley<br>Ed Quick<br>Bob Robbins |

**Data Sharing and Intellectual Capital Working Group Teleconference, September 30th, 2004, 2:00 pm EDT**

| | |
|---|---|
| **Group Responsibilities** | Wendy asked the group to review the draft list of expectations for teams assigned to each topic. Responsibilities outlined below are tentative, and subject to confirmation by DSIC WG members:<br>1, Prioritize and schedule meeting sessions<br>2. Develop use cases<br>3. Cross WS coordination<br>4. Prepare outlines<br>5. Identify existing resources<br>6. Perform additional research and organize meetings with outside experts as needed<br>7. Update outlines when appropriate<br>8. Submit discussion drafts for group review<br>Howard Bilofsky thought that the teams should establish timelines based on their perceived level of urgency and lay out a process for communication. Bob reiterated his view that the model of having a face-to-face meeting with active discourse is useful approach when immediate results are required.<br>Pat pointed out that every research institution has an IRB/HIPAA compliance office of some sort and recommended that team1 take advantage of that expertise. Wendy thought this was a good example of the fact that each team will need subject matter expertise to substantiate its positions. She emphasized that the teams will need to coordinate cross-workspace efforts on a systematic basis. Pat suggested that it would be useful for teams to solicit use cases with specific examples from each WS/WG and include them as appendices to the white papers. An example of a cross-WS effort is the the Clinical Trials Workspace -Lab Interface SIG, which deals with HIPAA issues regarding data and biospecimens. |
| **Items for next meeting** | Phan and Wendy will follow up by distributing to the WG a reformulation of the topics based on the discussion during the teleconference and team assignments based on responses from the group. They will also coordinate with the teams to develop agenda items for the next meeting. |

**Data Sharing and Intellectual Capital Working Group Teleconference, September 30th, 2004, 2:00 pm EDT**

| Action Items | Name | Action Item | Date Due | Notes |
|---|---|---|---|---|
| | Phan/Wendy | Topics/Team assignments | 10/8/04 | |
| | Team members | Outline of issues | ?? | Team members need to agree |