



Office of Biorepositories and Biospecimen Research  
National Cancer Institute  
National Institutes of Health  
U.S. Department of Health and Human Services

## **Custodianship and Ownership Issues in Biospecimen Research Symposium-Workshop**

*October 4-5, 2007*

*Hilton Washington DC/Rockville Executive Meeting Center  
1750 Rockville Pike  
Rockville, MD 20852*

### **AGENDA**

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***Statement of the Meeting:** This landmark symposium-workshop is convened to provide recommendations for best practices for the custodianship of human biospecimens and associated data at NCI-supported resources. The meeting brings together leaders from the academic community, private sectors, patient advocacy groups, and government agencies. The ultimate goal is to advance research on biospecimens and associated data while protecting the interests of human research participants.*

#### **Thursday, October 4**

7:00 a.m. - 8:00 a.m.	<b>Registration</b>	
8:00 a.m.	<b>Opening of the Meeting</b>	
8:00 a.m. - 12:10 p.m.	<b>Plenary Session I</b>	<i>Plaza Ballroom</i>
8:00 a.m. - 8:30 a.m.	<b><i>Welcome and Presentation of the Meeting Objectives</i></b> Anna D. Barker, Ph.D. National Cancer Institute, NIH	
8:30 a.m. - 9:00 a.m.	<b><i>Evidence-Based Best Practices for NCI-Supported Resources</i></b> Carolyn C. Compton, M.D., Ph.D. National Cancer Institute, NIH	
9:00 a.m. - 9:30 a.m.	<b><i>Chair's Remarks</i></b> Lori B. Andrews, J.D. Chicago-Kent College of Law	
9:30 a.m. - 10:15 a.m.	<b><i>Keynote Address: Ethical Considerations in Establishing Custodianship Principles</i></b> Arthur L. Caplan, Ph.D. University of Pennsylvania	



**Thursday, October 4 (continued)**

2:50 p.m. - 4:00 p.m.

**Session I**

***Breakout 1: Considerations for Research Participants,  
Investigators, and Institutions***

*Jefferson Room*

*Session Focus: Provides recommendations concerning what custodial information to include in the informed consent document for biospecimen collection; elements of custodianship plans that should be considered by investigators and institutes in grants and contracts; and plans for handling and disposition of biospecimens and associated data in various scenarios such as termination of active grant support or relocation of the principal investigator.*

Chair: Ellen Wright Clayton, M.D., J.D.  
Vanderbilt University

Co-Chairs: John M. Jessup, M.D.  
National Cancer Institute, NIH

Nicole C. Lockhart, Ph.D.  
National Cancer Institute, NIH

Writer: David W. Conrad, Ph.D., M.B.A.

Participants: Margaret A. Anderson, M.A.; Marianna J. Bledsoe, M.A.;  
Carolyn C. Compton, M.D., Ph.D.; Lynn G. Dressler,  
Dr.P.H.; Glen Drew, J.D.; Daniela S. Gerhard, Ph.D.;  
Nancy M.P. King, J.D.; Mary Anderlik Majumder, Ph.D.,  
J.D.; Jerry A. Menikoff, M.D., J.D.; Jon F. Merz, Ph.D.,  
J.D.; P. Pearl O'Rourke, M.D.; John P. Potter, M.D.;  
Alicia Sable-Hunt, M.B.A., R.N.; Richard L. Schilsky,  
M.D.; Karl Schwartz, M.F.A.; Sheila E. Taube, Ph.D.;  
Mark A. Watson, M.D., Ph.D.; Thomas M. Wheeler,  
M.D.; Celeste Whitewolf, J.D.

**Thursday, October 4 (continued)**

***Breakout 2: Financial Conflicts of Interest***

*Roosevelt Room*

*Session Focus: Provides recommendations concerning whether to disclose financial conflicts of interest to research participants; custodial rights and control of biospecimens in public-private partnerships; and acceptable cost-recovery arrangements in public-private partnerships.*

Chair: H. Kim Lyerly, M.D.  
Duke University

Co-Chair: Linda K. Weiss, Ph.D.  
National Cancer Institute, NIH

Writer: Amy Iadarola, M.A.

Participants: Debra Aronson, J.D.; L. Michelle Bennett, Ph.D.; Gregory A. Curt, M.D.; Martin L. Ferguson, Ph.D.; Michele B. Goodwin, J.D., LL.M.; Renata B. Greenspan, M.D.; Stephen C. Groft, Pharm.D.; Bumni Mfuko; Helen Moore, Ph.D.; Yaffa Rubinstein, Ph.D.; Julie A. Schneider, D.Phil.; Westley Sholes, M.P.A.; Barbara Spalholz, Ph.D.

***Breakout 3: Intellectual Property***

*Wilson Room*

*Session Focus: Provides recommendations concerning who should have the custodial obligation to influence patenting and licensing decisions and distribute income derived from biospecimen research discoveries; the appropriate circumstances for commercialization of biospecimens; and whether information related to potential patenting of discoveries should be disclosed in the informed consent.*

Chair: Aaron X. Fellmeth, J.D., M.A.  
Arizona State University

Co-Chair: Jeffrey W. Thomas, Ph.D.  
National Cancer Institute, NIH

Writer: Mythreyi Shastri, Ph.D., M.Sc.

Participants: Elaine L. Brock, J.D., M.H.S.A.; Charlotte Holden, J.D.; Andrew M. Hruszkewycz, M.D., Ph.D.; J.P. Kim, J.D., M.B.A.; Jason Levine, M.D.; Irina A. Lubensky, M.D.; John R. Mills, J.D.; Wendy Patterson, J.D.; Mary Lou Smith, J.D.; Susan J. Stayn, J.D.; Asad Umar, D.V.M., Ph.D.; Jim Vaught, Ph.D.; Susan E. Wallace, Ph.D.

**Thursday, October 4 (continued)**

***Breakout 4: Access to Products and Benefits***

*Truman Room*

*Session Focus: Provides recommendations concerning the rights of research participants to developments arising from biospecimen research; the types of benefits and products that can be accessed by research participants; and appropriate mechanisms for the release of research results to research participants.*

Chair: Timothy J. O’Leary, M.D., Ph.D.  
Department of Veterans Affairs

Co-Chair: Karen E. Pitt, Ph.D.  
National Cancer Institute, NIH

Writer: Noreen Teoh, M.P.H.

Participants: Roger L. Aamodt, Ph.D.; Christine D. Berg, M.D.; Bette-Jane Crigger, Ph.D.; Ian Fore, D.Phil.; Claudia M. Gaffey, M.D.; John W. Gillespie, M.D.; Marianne K. Henderson, M.S.; Charles B. Inlander; David R. Karp, M.D., Ph.D.; Karen J. Maschke, Ph.D.; Matthew Moore, M.P.P.; James A. Robb, M.D.; Dale P. Sandler, Ph.D.; Karen Smith Thiel, Ph.D., J.D.

4:00 p.m. - 4:15 p.m. **Coffee Break**

4:15 p.m. - 5:30 p.m. ***Session I (continued)***

***Breakout 1: Considerations for Research Participants, Investigators, and Institutions***

*Jefferson Room*

Chair: Ellen Wright Clayton, M.D., J.D.  
Vanderbilt University

Co-Chairs: John M. Jessup, M.D.  
National Cancer Institute, NIH

Nicole C. Lockhart, Ph.D.  
National Cancer Institute, NIH

Writer: David W. Conrad, Ph.D., M.B.A.

***Breakout 2: Financial Conflicts of Interest***

*Roosevelt Room*

Chair: H. Kim Lyerly, M.D.  
Duke University

Co-Chair: Linda K. Weiss, Ph.D.  
National Cancer Institute, NIH

Writer: Amy Iadarola, M.A.

**Thursday, October 4** (continued)

***Breakout 3: Intellectual Property***

*Wilson Room*

Chair: Aaron X. Fellmeth, J.D., M.A.  
Arizona State University

Co-Chair: Jeffrey W. Thomas, Ph.D.  
National Cancer Institute, NIH

Writer: Mythreyi Shastri, Ph.D., M.Sc.

***Breakout 4: Access to Products and Benefits***

*Truman Room*

Chair: Timothy J. O’Leary, M.D., Ph.D.  
Department of Veterans Affairs

Co-Chair: Karen E. Pitt, Ph.D.  
National Cancer Institute, NIH

Writer: Noreen Teoh, M.P.H.

5:30 p.m.

**Adjourn for the Day**

**Friday, October 5**

8:00 a.m. - 10:30 a.m.

**Plenary Session III**

*Plaza Ballroom*

**Reports From Breakout Session Chairs**

Reports, 20 minutes; Q&A, 10 minutes

Chair: Lori B. Andrews, J.D.  
Chicago-Kent College of Law

8:00 a.m. - 8:30 a.m. ***Considerations for Research Participants, Investigators, and Institutions***

Ellen Wright Clayton, M.D., J.D.  
Vanderbilt University

8:30 a.m. - 9:00 a.m. ***Financial Conflicts of Interest***

H. Kim Lyerly, M.D.  
Duke University

9:00 a.m. - 9:30 a.m. ***Intellectual Property***

Aaron X. Fellmeth, J.D., M.A.  
Arizona State University

9:30 a.m. - 10:00 a.m. ***Access to Products and Benefits***

Timothy J. O'Leary, M.D., Ph.D.  
Department of Veterans Affairs

10:00 a.m. - 10:30 a.m. ***Overall Discussions***

All Panel

10:30 a.m. - 10:45 a.m.

**Coffee Break**

10:45 a.m. - 12 noon

**Breakout Sessions**

Chair: Lori B. Andrews, J.D.  
Chicago-Kent College of Law

Co-Chair: Rihab R. Yassin, Ph.D.  
National Cancer Institute, NIH

***Session II***

*Session Focus: Discussions of unresolved issues; overlaps between sessions; and new issues to consider.*

***Breakout 1: Considerations for Research Participants, Investigators, and Institutions***

*Jefferson Room*

Chair: Ellen Wright Clayton, M.D., J.D.  
Vanderbilt University

Co-Chairs: John M. Jessup, M.D.  
National Cancer Institute, NIH

Nicole C. Lockhart, Ph.D.  
National Cancer Institute, NIH

Writer: David W. Conrad, Ph.D., M.B.A.

**Friday, October 5 (continued)**

***Breakout 2: Financial Conflicts of Interest***

*Roosevelt Room*

Chair: H. Kim Lyerly, M.D.  
Duke University

Co-Chair: Linda K. Weiss, Ph.D.  
National Cancer Institute, NIH

Writer: Amy Iadarola, M.A.

***Breakout 3: Intellectual Property***

*Wilson Room*

Chair: Aaron X. Fellmeth, J.D., M.A.  
Arizona State University

Co-Chair: Jeffrey W. Thomas, Ph.D.  
National Cancer Institute, NIH

Writer: Mythreyi Shastri, Ph.D., M.Sc.

***Breakout 4: Access to Products and Benefits***

*Truman Room*

Chair: Timothy J. O'Leary, M.D., Ph.D.  
Department of Veterans Affairs

Co-Chair: Karen E. Pitt, Ph.D.  
National Cancer Institute, NIH

Writer: Noreen Teoh, M.P.H.

12 noon - 1:00 p.m.

**Meeting Finale and the Next Step**

**Conclusions From Breakout Sessions**

Chair: Lori B. Andrews, J.D.  
Chicago-Kent College of Law

12 noon - 12:10 p.m. ***Considerations for Research Participants, Investigators, and Institutions***  
Ellen Wright Clayton, M.D., J.D.  
Vanderbilt University

12:10 p.m. - 12:20 p.m. ***Financial Conflicts of Interest***  
H. Kim Lyerly, M.D.  
Duke University

12:20 p.m. - 12:30 p.m. ***Intellectual Property***  
Aaron X. Fellmeth, J.D., M.A.  
Arizona State University

**Friday, October 5 (continued)**

12:30 p.m. - 12:40 p.m. **Access to Products and Benefits**  
Timothy J. O'Leary, M.D., Ph.D.  
Department of Veterans Affairs

12:40 p.m. - 12:50 p.m. **Closing Remarks**  
Lori B. Andrews, J.D.  
Chicago-Kent College of Law

12:50 p.m. - 1:00 p.m. **Meeting Conclusion**  
Carolyn C. Compton, M.D., Ph.D.  
National Cancer Institute, NIH

Rihab R. Yassin, Ph.D.  
National Cancer Institute, NIH

1:00 p.m.

**Adjournment**