



INFORMED CONSENT MODELS/TEMPLATES

for Rare Disease Registries Linked to Biorepositories

December 13–14, 2010 • Hilton Washington DC/Rockville Hotel & Executive Meeting Center • Rockville, MD

DAY 1 — MONDAY, DECEMBER 13

Working Group Goals:

1. Recommend template(s) for short, simple, and clear informed consent for patient registries
2. Recommend elements to be included in informed consent for patient registries
3. Recommend what type of information and material should be available/provided to the patients before consenting

8:00 A.M. REGISTRATION AND CONTINENTAL BREAKFAST

9:00 A.M. Opening Remarks and Welcome
Stephen C. Graft, Pharm.D. — Director, Office of Rare Diseases Research (ORDR), National Institutes of Health (NIH)

9:15 A.M. Order of the Day

PRESENTATIONS

- 9:20 A.M. Keynote Speaker**
Opportunities and Challenges of Registries and Repositories — Perspectives from the National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy
Richard T. Moxley, M.D. — University of Rochester
- 9:40 A.M. Public Access to Deidentified Rare Disease Patient Data**
Clement J. McDonald, M.D. — National Library of Medicine, NIH
- 9:55 A.M. EPIRARE: The Development of Rare Diseases Epidemiological Data from Patient Registries**
Domenica Taruscio, M.D. — National Centre Rare Diseases, Istituto Superiore di Sanità
- 10:15 A.M. BREAK**



SESSION I

Informed Consent for Patient Participation in the Patient Registry

Session Leaders: *Barbara I. Karp, M.D.* — National Institute of Neurological Disorders and Stroke, NIH and *Patricia A. Marshall, Ph.D.* — Case Western University

10:30 A.M. Introduction

- Background information about GRDR
- Different types of patient registries
Yaffa Rubinstein, Ph.D. — ORDR, NIH

10:40 A.M. Discussion Points

- Elements of the informed consent
 - Required elements
 - Supplemental elements
- Process of consent: approaches and methods
- Ongoing consent/right of withdrawal
- Q&A

1:00 P.M. WORKING LUNCH — Presentation

Emphasizing the Potential for Discovery of New Information While Assuring Trust in the Informed Consent Process

Frederick Kaskel, M.D., Ph.D. — Children's Hospital at Montefiore

2:00 P.M. Session I Discussion

- Special populations
 - Minors
 - Adults without consent capacity
 - Other
- Documentation of informed consent
- Future communication, especially to recruit for clinical trials
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4:00 P.M. BREAK

4:15 P.M. Session I Summary

5:30 P.M. BREAK

6:00 P.M. WORKING DINNER — Keynote Speaker

An Integrated Approach to Data and Specimen Sharing for Vulnerable Populations: The National Children's Study as a Case Study

Steven Hirschfeld, M.D., Ph.D. — Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH

7:15 P.M. Day 1 Summary/Closing Remarks

Yaffa Rubinstein, Ph.D. — ORDR, NIH



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DAY 2 — TUESDAY, DECEMBER 14

- 7:30 A.M.** **REGISTRATION AND CONTINENTAL BREAKFAST**
- 8:00 A.M.** **Order of the Day**
- 8:05 A.M.** **Keynote Speaker: When is Open-Ended Consent Adequately Informed?**
Jerry Menikoff, M.D., J.D. — Office for Human Research Protections

SESSION II

Informed Consent for Patient Donating of Biospecimens for Research

Session Leaders: *Nicole Lockhart, Ph.D.* — National Cancer Institute, NIH and *Julie Kaneshiro, M.A.* — Office for Human Research Protections

- 8:25 A.M.** **Discussion**
- How biospecimen consent differs from registry consent
 - Consent process
 - Who should or should not be involved in the informed consent process
 - Approaches to obtaining consent
 - Consent content
 - Types of consent for biospecimen use (open, tiered, restricted)
 - Return of results to contributors, especially genetic test results
 - Ongoing consent/right of withdrawal
- 10:25 A.M.** **BREAK**
- 10:40 A.M.** **Discussion (continued)**
- Consent for nonbiological material
 - Imaging
 - Photos
 - Special populations
 - Minors
 - Adults without consent capacity
 - Other
 - Documentation of informed consent



- 12:40 P.M. WORKING LUNCH — Presentation**
Informed Consent for Children and Teenagers Turning Adults in Rare Disease Registries: A Clinical Point of View
Maurizio Scarpa, M.D., Ph.D. — University of Padova
- 1:40 P.M. Session II Summary**
- 2:30 P.M. Conclusions and Recommendations from Sessions I & II**
- 3:00 P.M. Adjourn**