3rd AFRICA CONFERENCE ON ETHICAL ASPECTS OF CLINICAL RESEARCH IN DEVELOPING COUNTRIES

March 19-21, 2003
Kampala, Uganda

Tuesday, March 18, 2003

Evening            Welcome Reception

Wednesday, March 19, 2003

8:30-9:00 am         Formal Welcome

9:00-9:45 am         A Framework for the Ethics of Clinical Research
                     Ezekiel J. Emanuel, M.D., Ph.D.
                     NIH, USA

Readings: Emanuel E, Wendler D, Grady C. What Makes Clinical Research Ethical?
The Nuremberg Code
The Belmont Report
Flaherty MP, Struck D. Life By Luck Of The Draw. The Body Hunters:
9:45-10:00 am  Case about Randomization and Placebo Controls  
Banson Barugahare, M.Phil.  
Makerere University, Uganda

10:00-10:45 am  The Ethics of Randomization and Placebo Controls  
Reidar K. Lie, MD, PhD  
NIH

Readings:  

10:45-11:00 am  Break

11:00-11:15 am  Case about Risks and Benefits  
Joseph Ochieng, MD
Makerere University, Uganda

11:15-12:00 pm The Ethics of Risks and Benefits
Reidar K. Lie, MD, PhD
NIH


12:00-1:30 pm Lunch

1:30-1:45 pm Case about Recruitment and Incentives
TBA

1:45-2:30 pm The Ethics of Subject Recruitment
David Wendler, PhD
NIH


2:30-3:00 Break

3:00-3:45 pm The Ethics of Conflicts of Interest
Ambrose Talisma, MD
Ministry of Health, Uganda

Thompson D. Ethics in Congress: From Individual to Institutional

3:45- 4:00 pm  Case about Stored Biological Samples
4:00-4:45 pm  The Ethics of Research with Stored Biological Samples
              Diana Atwine, MD
              JCRC, Uganda


**Thursday, March 20, 2003**

8:30-8:45 am  Case About Individual Informed Consent
              TBA

8:45-9:30 am  The Ethics of Informed Consent
              David Wendler, PhD
              NIH

           Berg JW, et al. The Legal Requirements for Disclosure and

Guidelines for Writing Informed Consent Documents, OHSR, NIH.

Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials, NCI, NIH.

9:30 - 10.00 am  Break

10:00 - 10:30 am Case about Community Mobilization and Consent

Vickee Tallo, PhD
Research Institute for Tropical Medicine,
The Philippines

10:30-12:00 pm Community Mobilization and Consent

Hanna Nohynek, MD, PhD,
Finland

12:00  Lunch

Afternoon and Evening  Free Time and Optional Excursion

**Friday, March 21, 2003**

8:30-9:15 am Function and Performance of Ethical Review

Reidar K. Lie, MD, Ph.D
NIH


9:15-10:30 am Mock IRB

Ezekiel Emanuel, MD, PhD
NIH

10:30-11 Break
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<tr>
<th>Time</th>
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<td>11-11:45</td>
<td>Access to Treatment in Clinical Trials</td>
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<td>Cathy Slack</td>
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<td>11:45-12:30</td>
<td>Access to Treatment in Clinical Trials</td>
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<td>Henry Richardson, PhD</td>
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<td><strong>Readings</strong></td>
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<td>Glantz L., Annas G., et al. Research in Developing Countries: Taking</td>
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<td>Shapiro HT, Meslin EM. Ethical Issues In the Design and Conduct of</td>
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<td>Clinical Trials in Developing Countries. *New England Journal of</td>
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<td>Medicine* 2001; 345:139-141</td>
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<td>Participants in the 2001 Conference on Ethical Aspects of Research</td>
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<td>Countries <em>Science</em> Dec 13 2002; 2133-2134</td>
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<td>12:30-13:30</td>
<td>Lunch</td>
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<td>13:30-15:00</td>
<td>Community Consent: Should the idea be abandoned? Reidar K. Lie, MD, PhD.</td>
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<td><strong>Evening</strong></td>
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<td>Concluding Reception and Dinner</td>
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