International Symposium, on Ethical Issues Related to Biomedical Research Involving Human Subjects – Building and Operating of the Ethics Committee

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Objective

• Overview of US FDA in China
  • Who are we?
  • What will we do in China

• Brief comments on the role of the ethics committee from a regulatory prospective
Organization of FDA

Department of Health & Human Services

Office of Chief Counsel

Office of International Programs

Office of Policy, Planning & Budget

Office Legislation

Office of Chief Scientist

Food & Drug Administration
Office of the Commissioner

CDER

CDRH

CBER

CVM

CFSAN

ORA

Dec. 2009

SCRC
US Food and Drug Administration in China
November 2008 Official Opening
The Ambassador, Secretary of HHS, Commissioner, and the US FDA China Staff

Dec. 2009

11/19/2008
Who?

Director
Christopher Hickey

Deputy Director
Michael Kravchuk

Assistant Director
Irene Chan

Assistant Director
Brenda Uratani

Medical Research Scientist
WANG Lixia

Administrative Assistant
FU Zimei (Mandy)

Beijing

Dec. 2009

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Importance of Ethics Committees in Ensuring Human Subject Protection
Pressures

- **Industry**
  - Stock Holders
  - Bottom Line
  - First to Market
  - Patent
  - Jobs, their’s

- **Clinical Investigators**
  - Publish
  - Hospital
  - Bottom Line
  - Prestige
  - Free vacation
  - Ego
Role of the Ethics Committee

“.... designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects....” 21 CFRR 56.102 (g)
What Subject REALLY hear.

Blood blah blah 100 blah blah will be taken from you by
blah blah blah blah blah blah blah
learn blah blah blah blah blah blah blah
blah your blood blah.
Subject’s Contribution

• Information
• Time
• Themselves

• Extreme Sacrifice
Ways to Ensure Subject Protection

- Review study protocols objectively to maximize benefit, and minimize risk
- Ensure informed consent form accurately reflects the study protocol
- Ensure informed consent form is kept current
- Ensure informed consent form is written in understandable language
Ways to Ensure Subject Protection

- Stay current on the latest medical treatments
- Audit the clinical investigation
- Observe the consent process
- Review each study as if your relatives (grandparents, parents, children, siblings, etc) are participating in the study
- Be INDEPENDENT
Ethics committee is the first line of defense against the unethical, overzealous companies, clinical research associates, AND clinical investigator!
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Questions?

Drug  GCP, GLP, GMP Questions
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GLP, GCP, Device GMP Questions:
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