Informed Consent Guidance for Gene Transfer Research

RAC Meeting
Washington, D. C.
December 4, 2003

Nancy King, J.D.
Co-Chair
Informed Consent Working Group

Intended Users of Guidance

- Primary intended user – Principal Investigators
- Additional potential users – IRB and IBC members, sponsors, potential research participants, general public

Nature of the Guidance

- What it is:
  - An educational tool
  - An information resource
- What it is not:
  - An amendment to Appendix M
  - New policy

Development Process

- Developed and revised several draft iterations in the past year
- Received user input in Spring 2003
- Presented to the RAC in June 2003
- Incorporated RAC and public suggestions
- Posted on OBA website in December 2003

Acknowledgements

ICWG Members

- Baruch Brody, Baylor College of Medicine (co-chair)
- Nancy King, University of North Carolina (co-chair)
- James Childress, University of Virginia
- Bernie Lo, University of California, SF
- Sue Levi-Pearl, Tourette's Syndrome Ass'n
- Diane Wara, University of California, SF

Agency Representatives

- Kristina Borror (OHRP)
- Cynthia Rask (FDA)

OBA Staff

- Suzanne Goodwin
- Katherine Heineman
- Amy Patterson
- Stephen Rose
- Allan Shipp
- Courtney Storm

Accessing this Resource on the Web

- Connect to:

  http://www4.od.nih.gov/oba/rac/ic/

Demonstration

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