

# Health Literacy and Human Subject Protection: OHRP Perspective

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September 14, 2006

Roundtable on Health Literacy

Institute of Medicine

Washington, DC

# What accounts for low health literacy?

low capacity to read, write, express oneself

lack of understanding among literate people

- 1 concepts of health, therapy, prevention

vulnerable groups

- 1 young/elderly, mentally handicapped/decisionally impaired, prisoners, emergency situation patients

"literate" with misinformation

- 1 Internet, representing research as treatment

# OHRP initiatives

## Outreach to the public

- 1 Tri-fold Becoming A Research Volunteer: It's Your Decision
  - English, Spanish, Vietnamese

## Outreach to IRB folks, investigators, institutional officials

- 1 guidances
- 1 Qs & As - including informed consent
- 1 constant discussion with IRB folks, etc.
- 1 conferences and workshops
- 1 over 100 presentations per year
- 1 Secretary's Advisory Committee on Human Research Protection

# Flexibility with informed consent

Process, not just a document

Assent of children

Legally Authorized Representatives

Waiver - emergency room research

Short form

# What we need

More research - how to make improvements

IC documents no longer than necessary

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